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In The

Supreme Court of the United States

October Term, 1975

No. 75-1612

ETHYL CORPORATION,

Petitioner,

v.

ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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ETHYL CORPORATION,

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ENVIRONMENTAL PROTECTION AGENCY,

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The Petitioner, Ethyl Corporation (a Virginia corporation), respectfully prays that a Writ of Certiorari issue to review the judgment and opinion of the United States Court of Appeals for the District of Columbia Circuit entered in this proceeding on March 19, 1976.

OPINIONS BELOW

The majority and dissenting opinions of the Court of Appeals are contained in the Joint Appendix being separately filed with the Court on behalf of all of the petitioners

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in the proceeding below.* The opinions have not yet been published in the official reports, but they have been published at 8 ERC 1785.

JURISDICTION

In Opinions issued January 28, 1975 (7 ERC 1353), a panel of the Court of Appeals for the District of Columbia Circuit ruled by a vote of two to one that the Respondent's regulations, the subject of review in this proceeding, should be set aside. On March 17, 1975, the Court of Appeals granted Respondent's petition for a rehearing *en banc* and vacated the panel opinions. The final judgment of the Court of Appeals, affirming Respondent's regulations by a five to four vote, was entered on March 19, 1976. Upon joint motion of all of the petitioners in this proceeding and the Respondent, the Court of Appeals entered an order on April 7, 1976, staying its mandate through May 6, 1976, pending the filing of a petition for a writ of certiorari and a final determination thereon by this Court.

This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

QUESTIONS PRESENTED

This case involves a challenge by Petitioner and others to the validity of regulations issued by Respondent under Section 211(c)(1)(A) of the Clean Air Act requiring the phased reduction of lead additives ("lead antiknocks") in

* The Joint Appendix contains the final opinions of the Court of Appeals in the cases of Ethyl Corp. v. EPA (No. 73-2205), PPG Industries, Inc. v. EPA (No. 73-2268), E. I. DuPont de Nemours & Co. v. EPA (No. 73-2269), Nalco Chemical Co. v. EPA (No. 73-2270), and National Petroleum Refiners Ass'n v. EPA (No. 74-1021). The Petitioner understands that separate petitions for a writ of certiorari are being filed by PPG Industries, DuPont, Nalco and the National Petroleum Refiners Association.

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motor gasoline. The case raises difficult and complex issues of national significance that were decided by a closely divided Court of Appeals whose lengthy and sharply conflicting opinions demonstrate the need for review and final decision by this Court. Specifically, the questions presented are:

1. Whether the Administrator of the Environmental Protection Agency has been empowered by Section 211 of the Clean Air Act to assess hypothetical and speculative risks and make "essentially legislative policy judgments," as the majority of the Court of Appeals held, even where the available medical and scientific evidence (which is voluminous) is admittedly inconclusive and fails to establish that the emission products of lead antiknocks in gasoline cause any harm to the public health.

2. Whether, in reviewing agency rule-making in the area of environmental control, the courts should be limited to a finding of minimal rationality on the part of the agency, as held by the majority below, without inquiry into the propriety of the methodology employed by the agency in assessing the evidence or the reasonableness of the procedures it followed in formulating its regulatory program.

3. Whether, notwithstanding the requirements of due process and the Administrative Procedure Act, the Administrator may issue regulations based in large part upon preliminary, untested studies and new data as to which interested parties have not been given notice or the opportunity for meaningful comment.

STATUTES AND REGULATIONS INVOLVED

The pertinent provisions of the Clean Air Act (42 U.S.C. §§ 1857c-3, 1857c-4, 1857f-1, 1857f-6c(c)), the Adminis-

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trative Procedure Act (5 U.S.C. § 553), and the regulations involved (40 C.F.R. §§ 80.1, 80.2(c), 80.20, 80.25, 80.26) are set forth in Appendix A to this petition.

STATEMENT OF THE CASE

Background of Lead Antiknocks

The regulations under review[1] were promulgated by the Respondent, the Environmental Protection Agency, under Section 211(c)(1)(A) of the Clean Air Act, 42 U.S.C. § 1857f-6c(c). The Regulations require the phased reduction over five years by 60-65% of lead antiknocks used in all motor gasoline sold in the United States. 40 C.F.R. §§ 80.1, .2, .20, .25, .26, 38 Fed. Reg. 33734-33741 (1973) (A. at 1-9).

Lead antiknocks have been added to motor gasoline since 1923 to increase the octane rating of gasoline for use in high compression engines that operate with greater efficiency. A large industry, providing thousands of jobs and owned by thousands of private investors, has grown up to supply lead antiknocks to gasoline refiners.

Lead antiknocks serve as "energy extenders," enabling the refiner to produce more gasoline of a higher octane from a given amount of crude oil at a lower cost. The saving of crude oil from the use of lead antiknocks is 5-6%. The use of lead antiknocks over the years has resulted in the saving of billions of barrels of essential crude oil and billions of dollars by the motoring public in the United States. Today, in the face of continuing energy problems, the substantial elimination of lead antiknocks will greatly increase the use of crude oil and the cost of gasoline (placing substantial reliance upon imported supplies and further draining our bal-

[1] Judicial review is expressly authorized under Section 307(b)(1) of the Clean Air Act, 42 U.S.C. § 1857h-5(b)(1).

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ance of payments), require the substitution of aromatic compounds which result in the emission of carcinogens and compel the expenditure of billions of dollars by the refining industry to make the changes in equipment necessary to manufacture commercial gasoline without lead antiknocks.

The effects on the public health of the use of lead antiknocks in gasoline have been the subject of continued study and monitoring for more than fifty years, much of it planned, sponsored, financed and supervised by governmental agencies. From all this study, not one person has been found to have any identifiable adverse health effects from lead emitted from motor vehicle exhausts. Neither the Respondent nor the majority of the Court of Appeals have shown otherwise.

Background of Regulations

The Respondent issued the regulations in question under Section 211(c)(1)[2] of the Clean Air Act Amendments of 1970, which in precise terms authorizes the EPA Administrator to:

> "control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive for use in a motor vehicle or motor vehicle engine (A) *if any emission products of such fuel or fuel additive will endanger the public health or welfare* . . . ." (Emphasis added.)[3]

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[2] 42 U.S.C. § 1857f-6c(c)(1).

[3] Section 211 also authorizes the regulation of fuel additives upon a finding that the additive significantly impairs the performance of an emission control device in general use. Regulations based on that ground requiring the general availability of at least one grade of unleaded gasoline were issued in early 1973, 40 C.F.R. §§ 80.1-.24, and were upheld by the D. C. Circuit in *Amoco Oil Co.* v. *EPA*, 501 F.2d 722 (D.C. Cir. 1974). Those regulations are not in issue in this proceeding.

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Within a month after Section 211 was enacted by Congress, the Respondent publicly announced that it was reviewing the medical and scientific data applicable to the health effects of lead, and that regulations to reduce the lead content of motor fuel were "anticipated."[4] Proposed regulations were first published on February 23, 1972,[5] accompanied by a document purporting to summarize the medical and scientific basis for the proposal.[6] EPA invited comments on the proposal and conducted public hearings on the subject during the Spring of 1972 in Washington, Dallas, and Los Angeles.

Thereafter, on January 10, 1973, EPA issued a new set of proposed regulations[7] as well as a completely revised health document.[8] The Respondent again invited public comment, citing the fact that the agency's basis for the regulations "has been substantially revised." 38 Fed. Reg. 1254 (1973).

On October 28, 1973, a panel of the Court of Appeals below (Judges Wright and McGowan), in an unreported order entered in response to a motion filed in *Natural Resources Defense Council* v. *EPA*, D.C. Cir. No. 72-2233, directed the Respondent to reach a final decision on whether to regulate the lead content of fuel for health reasons *within thirty days*. The final regulations were promulgated on November 28, 1973, accompanied by a third —and again substantially revised—review of the available

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[4] 36 Fed. Reg. 1486 (Jan. 30, 1971) (A. at 26).

[5] 37 Fed. Reg. 3882 (1972) (A. at 22).

[6] R. Doc. No. 13 (A. at 292), revised with R. Doc. No. 10 (A. at 254).

[7] 38 Fed. Reg. 1258 (1973) (A. at 14).

[8] R. Doc. No. 9 (A. at 158).

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medical and scientific data (hereafter referred to as the "Third Health Document").[9]

Court of Appeals Review

On the day the final regulations were published in the Federal Register,[10] December 6, 1973, the Petitioner herein promptly filed a petition to review the regulations with the Court of Appeals for the District of Columbia Circuit.[11] Similar petitions were also filed by PPG Industries, Inc., E. I. DuPont de Nemours & Co., Nalco Chemical Co. and the National Petroleum Refiners Association.

The panel assigned to the case heard arguments on September 9, 1974, and on December 20, 1974, the panel, one judge dissenting, ordered the regulations set aside. Extensive opinions (73 pages for the majority; 96 pages for the dissent) were issued January 28, 1975.

On March 17, 1975, the Court of Appeals granted the Respondent's petition for a rehearing *en banc*, and the panel judgment and opinions were vacated. Reargument was held May 30, 1975 before eight judges of the Court of Appeals, Chief Judge Bazelon not being present. On March 19, 1976, the Court decided by a vote of five to four to affirm the regulations, issuing the five separate opinions contained in the Joint Appendix.

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[9] R. Doc. No. 7 (A. at 27).

[10] 38 Fed. Reg. 33734 (Dec. 6, 1973) (A. at 1).

[11] Section 307(b)(1) of the Clean Air Act specifies the D. C. Circuit as the exclusive forum for review of regulations issued under Section 211. 42 U.S.C. § 1857h-5(b)(1).

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REASONS FOR GRANTING THE WRIT

This case as no other before it calls into question the basic accountability of a federal administrative agency for its rule-making decisions in an area of environmental control that results in major economic and social impacts. As indicated by the vigorous opinions of the majority and the dissent below, the medical and scientific considerations involved in this case are complex and highly controversial.[12] The final outcome of this case will vitally affect the future of the entire lead additive industry, its employees and its stockholders. It will also have a direct and substantial effect on the refining industry and through it on our national energy policy.

The case requires an assessment of the propriety of the agency's regulatory action at three distinct, but related, levels: *First,* the statutory standard prescribed by Congress as a precondition for regulatory action; *second,* the methodology employed by the agency in assessing the available evidence; and *third,* the reasonableness of the procedures followed by the agency in its formulation and issuance of the regulations. At each of these levels the majority below accorded the agency the broadest possible discretion, thus effectively abdicating the court's role as an independent overseer of agency action. The majority was clearly motivated by some feeling that environmental regulations are entitled to special deference—indeed to virtual exemption from the normal rules designed to uncover and reverse arbitrary agency action. The majority has presented a "blank check" to the EPA for the future exercise of standardless, irreversible discretion affecting all areas of our national life. The

[12] Former EPA Administrator, William D. Ruckelshaus, publicly described the subject as "one of the most controversial complicated problems that I have ever had to deal with." R. Doc. No. 1094, Transcript of press briefing, p. 28 (A. at 2585).

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implications of this decision are so enormous as to require this Court's immediate attention.

A. The Majority Below Has Accorded the Respondent A Broad Policy Making Authority that Far Exceeds the Specific Power Congress Has Delegated to Respondent under Section 211 of the Clean Air Act.

The Respondent's authority to regulate the content of motor fuel derives solely from Section 211 of the Clean Air Act. That section, as a precondition to regulatory action against a fuel or fuel additive on health grounds, requires the Administrator to consider "all relevant medical and scientific evidence available to him."[13] Then, in unique language found nowhere else in the Clean Air Act, Section 211 provides that the Administrator may control or prohibit a fuel additive if the emission products of the additive *"will endanger"* the public health or welfare.

The meaning of "will endanger" is central to the question of Respondent's authority to issue the regulations. The Petitioner's position is that the "will endanger" standard, particularly when contrasted to the discretionary language of the other operative sections of the Act,[14] requires a threshold

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[13] Clean Air Act § 211(c)(2)(A), 42 U.S.C. § 1857f-6c(c)(2)(A). That section also requires the Administrator to consider "other technological or economically feasible means of achieving emission standards under Section 202."

[14] Section 108 authorizes the Administrator to issue air quality criteria for air pollutants that—"in his judgment"—adversely affect public health. 42 U.S.C. § 1857c-3. Section 109, in turn, requires the Administrator to prescribe national standards for such pollutants, allowing "an adequate margin of safety" for the protection of health. 42 U.S.C. § 1857c-4. Section 112 authorizes the promulgation of emission standards for air pollutants that—"in the judgment of the Administrator"—"may cause, or contribute to"—death or irreversible illness. 42 U.S.C. § 1857c-7. Section 202 authorizes the Administrator to prescribe new motor vehicle emission standards for any emissions which—"in his judgment"—are "likely to cause or to contribute to" air pollution endangering the public health. 42 U.S.C. § 1857f-1(a)(1).

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determination by the Administrator on the basis of factual data that the emission products are, to a high degree of probability, in fact harmful to health.[15] A conclusion that harm is merely possible, or even likely,[16] is not sufficient.

Neither Respondent nor the majority below suggest that Respondent has satisfied such a standard; they rather contend that far less is required. The majority thus reads Section 211 as conferring broad authority to assess the relative risks of underprotection against overprotection, and to make a policy choice based on a "fear of uncertain or unknown harm." Maj. op. at 56.[17] According to the majority, the Respondent has been given a "mandate to protect the public health," and through "speculation, conflicts in evidence, and theoretical extrapolation," the agency may base the regulations on a "slight or nonexistent data base." *Id.* at 47. It is noteworthy that Congress could easily have written such a "mandate" into the statute, but instead it chose to condition its delegation of a power upon a threshold factual determination by the agency that could be reviewed by the courts in the traditional way. As Judge Wilkey aptly observed in his dissent:

> "In essence, it is argued that the 'will endanger the public health . . .' standard is a delegation of quasi-legislative power to the Administrator and not a re-

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[15] "Endanger" means "to bring into danger or peril of *probable* harm or loss." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 748 (1971) (emphasis added).

[16] The distinction between "probable" and "likely" is clearly explained by Webster: "Something probable has so much evidence in its support or seems so reasonable that it commends itself to the mind as worthy of belief . . . . [I]n contrast with *probable, likely* does not as often or as definitely suggest grounds sufficient to warrant a presumption of truth . . . ." WEBSTER'S NEW DICTIONARY OF SYNONYMS 639 (1968) (emphasis in original).

[17] References to the majority opinion are to the opinion authored by Judge Wright contained in the Joint Appendix.

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> quirement that he reach a reasoned determination purely on the scientific and medical data." Dissenting op. at 55.[18]

In the judgment of the dissenters, such a construction by the majority "is to grant the plainest license for the wildest speculation."[19] Dissenting op. at 53. It is also contrary to the plain language used by the Congress in Section 211.

The Respondent has argued from the outset that, because its role in protecting the environment is so important, the agency should be released from the narrow confines of Section 211 and given more discretion to regulate automotive fuels (with fewer standards to meet). Amazingly, this request was not made to Congress, the sole constitutional source of all Respondent's authority, but to the Court of Appeals. And the majority affirmatively responded with a new judicial grant of authority, embodied in this broad assertion:

> "Regulators such as the Administrator must be accorded flexibility, a flexibility that recognizes the special judicial interest in favor of protection of the health and welfare of people, even in areas where certainty does not exist." Maj. op. at 46.

Then, as if to set a universal standard for all environmental rule-making, the majority concluded:

> "Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting be-

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[18] References to the dissenting opinion are to the opinion authored by Judge Wilkey contained in the Joint Appendix.

[19] Judge MacKinnon, in a separate dissenting opinion, agreed. "In my view the court's opinion in a number of respects exaggerates the Administrator's ability to act in the policy field without an underlying factual basis . . . . Thus I do not agree that Congress intended to vest the Administrator with authority to act on a speculative basis to the extent the court would allow." Opinion by MacKinnon, J., at 3.

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cause it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect." Maj. op. at 53-54.

The Petitioner submits that the specific and limited grant of statutory authority made by Congress, not a general expression by the courts of need for flexibility in areas affecting the public health, should govern the validity of an agency's rule-making in a given case. In certain areas, Congress has indeed conferred broad policy making discretion; in others, such as Section 211, it has not. In every case, however, the plain language employed by the Congress should control.[20] Certainly the courts should not extend their deference to administrative expertise to the point where the clear standards set by Congress may be ignored by the agency.

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[20] The significance of the particular language chosen for a statute is well illustrated by a comparison of Section 211 to the language and legislative history of the recently enacted Safe Drinking Water Act. That Act empowers the Administrator of EPA to prescribe standards for drinking water contaminants, which "in the judgment of the Administrator, may have any adverse effect on the health of persons . . . ." 42 U.S.C. § 300f(1)(B). In drafting the language of the Drinking Water Act, the House Interstate and Foreign Commerce Committee, the same House Committee that reported out the Clean Air Act Amendments of 1970, deliberately chose the word "may," rather than "will," which appears in Section 211, with purpose. As the Committee's report explains: "The words used by the Committee were carefully chosen. Because of the essentially preventive purpose of the legislation, the vast number of contaminants which may need to be regulated, and the limited amount of knowledge presently available on the health effects of various contaminants in drinking water, the Committee did not intend to require conclusive proof that any contaminant *will* cause adverse health effects as a condition for regulation of a suspect contaminant. Rather, all that is required is that the Administrator make a reasoned and plausible judgment that a contaminant *may* have such an effect." H. Rep. No. 93-1185, 93d Cong., 2d Sess., U.S. Code Cong. & Admin. News 6463 (1974) (emphasis in original).

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Where Congress intends for an agency to exercise broad policy making discretion, to err on the side of overprotection in an area "on the frontiers of scientific knowledge,"[21] Congress carefully selects words particularly suited to that purpose—"may," "likely," "risk,"[22] "in his judgment." By contrast, where the subject matter has been thoroughly studied for more than fifty years, as with lead antiknocks,[23] Congress understandably requires firm factual determinations, for which "will endanger" is more appropriate.

The point is that, the majority below notwithstanding, no generality is possible as to the standard to be applied in environmental rule-making. Congress has prescribed varying degrees of accountability for agency rule-making, and the appropriate standard in a given case can only be determined on the basis of the particular statutory language employed.[24] In the case of regulation of fuel content, which the majority concedes Congress expected Respondent to undertake only with trepidation,[25] Congress obviously contemplated that the agency would be held to a high degree of accountability.

The Respondent has not concluded that the evidence supports a "will endanger" conclusion for lead antiknocks.

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[21] Maj. op. at 54.

[22] For example, the toxic substances legislation now pending in Congress would authorize the Administrator of EPA to ban the use of any chemical substance that he finds "presents or is likely to present an unreasonable risk of injury to health or the environment." S. 3149, 94th Cong., 2d Sess., § 6, at 36.

[23] The majority argues that although lead additives have been studied for 50 years, emissions at present levels have existed only for the last 15-20 years. Maj. op. at 49. The record evidence shows that in spite of increases in airborne lead levels in the past 20 years, blood levels have not increased. R. Doc. No. 817, Fig. 1-1.

[24] For this reason, the majority's reliance on other cases, involving totally different statutes and different facts, is misplaced.

[25] Maj. op. at 16 n. 14.

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Indeed, Respondent has even conceded that the evidence does not establish a "reasonably clear causal relation" between ambient lead levels and adverse health effects, which according to Respondent precludes the setting of ambient air standards for lead under Section 108-109. EPA Supp. Brief at 15.[26] All the Respondent has suggested is that lead emissions from motor vehicles present a "significant risk of harm to the health of urban populations, particularly the health of city children . . . ," and this only when lead emissions from autos are combined with other sources of lead.[27]

Passing up the other, less rigorous options given to it under the Clean Air Act (ambient air standards, emission limitations), Respondent has taken the extreme action of regulating fuel content, at enormous costs to the petroleum industry and the motoring public, without any real knowledge that lead additives are a direct endangerment to public health, or that their reduction will have any measurable, beneficial effect.

Congress could take such action, perhaps; but Respondent cannot, at least not under Section 211. For purposes of this case and those that will inevitably follow, it is essential that this Court restrain administrative rule-making within its proper limits and restore the statutory standard laid down by Congress as the measure of regulatory power.[28]

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[26] The reference is to the supplemental brief filed by Respondent upon rehearing *en banc* in the Court of Appeals.

[27] 38 Fed. Reg. 33734 (Dec. 6, 1973) (A. at 1).

[28] As this Court has often reminded: "The deference owed to an expert tribunal cannot be allowed to slip into a judicial inertia which results in the unauthorized assumption by an agency of major policy decisions properly made by Congress." *NLRB* v. *Brown,* 380 U.S. 278, 291 (1965).

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B. The Majority Below Has So Narrowed The Scope of Judicial Review of Environmental Regulatory Actions As To Place Deference To Supposed Administrative Expertise Above The Standard of Reasoned Decision-Making.

Guided by the opinions of this Court in *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402 (1971),[29] and *Bowman Transp., Inc.* v. *Arkansas-Best Freight Sys. Inc.*, 419 U.S. 281 (1974),[30] the dissenting judges below carefully reviewed the record and concluded that Respondent had not taken the objective, hard look at the evidence that Section 211 and "reasoned decision-making" require,[31] and that the methodology employed by the agency in assessing the evidence had been arbitrary and capricious.[32]

The record in this case abounds with danger signals that Respondent had not been rational and principled in its approach to the subject. The waffling of positions during the three year rule-making through three separate health documents—alleging health *hazards* of lead in the first,[33]

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[29] The reviewing court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 416 (1971).

[30] "[T]hough an agency's finding may be supported by substantial evidence . . . it may nonetheless reflect arbitrary and capricious action. * * * The agency must articulate a 'rational connection between the facts found and the choice made.'" *Bowman Transp., Inc.* v. *Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 284-85 (1974).

[31] "Its supervisory function calls on the court to intervene . . . if the court becomes aware, especially from a combination of danger signals, that the agency has not really taken a hard look at the salient problems, and has not genuinely engaged in reasoned decision-making." *Greater Boston Television Corp.* v. *FCC*, 444 F.2d 841, 851 (D.C. Cir. 1970), *cert. denied*, 403 U.S. 923 (1971).

[32] "The Administrator must sustain the burden of adducing a reasoned presentation supporting the reliability of EPA's methodology." *International Harvester Co.* v. *Ruckelshaus*, 478 F.2d 615, 648 (D.C. Cir. 1973).

[33] R. Doc. No. 13, "Health Hazards of Lead," EPA (Feb. 23, 1971) (A. at 292).

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the health *effects* of lead in the second,[34] and finally the health *implications* of lead in the third[35]—indicated a grasping at straws in the evidence. The dissent recognized Respondent's prolonged struggle with the evidence as significant, saying:

> "This extended gestation period has significance in itself. Implicit in the administrative record generated by this three-year delay is the recognition by EPA that available scientific data did not provide a clear and certain basis for reaching the statutorily mandated conclusion, *i.e.*, that a 'fuel additive will endanger the public health or welfare.'
>
> "* * * The history of the regulations is really the history of the EPA Health Documents, a history of EPA's effort to discover somewhere, somehow, a scientific rationale which would withstand the unanimous criticism of the remainder of the government scientific community." Dissenting op. at 6-7.

The dissent was also struck by the fact that every other agency of the Federal Government that had studied the evidence—the Department of Health, Education and Welfare, the Department of the Interior, the Department of Commerce, the White House Office of Science and Technology, the National Institute for Occupational Safety and Health of the United States Public Health Service—had unanimously concluded that Respondent's position on the health effects of lead antiknocks was without support in the evidence.[36]

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[34] R. Doc. No. 9, "EPA's Position on the Health Effects of Airborne Lead" (Nov. 29, 1972) (A. at 158).

[35] R. Doc. No. 7, "EPA's Position of the Health Implications of Airborne Lead" (Nov. 28, 1973) (A. at 27).

[36] See the review of the other agency criticisms at Dissenting op. pp. 8-15. "Our analysis of the flaws in the Administrator's logic finds powerful support in the unaminity of conclusion of the independent scientific minds throughout the Government outside of EPA itself." Dissenting op. at 15-16.

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The record also contained numerous expressions of concern from the independent scientific community highly critical of Respondent's analysis and conclusions.[37] Within the agency itself, serious questions had been expressed as to the scientific soundness of any health basis for the regulations.[38]

The majority dismisses the contrary evidence and critical comment with the conclusion that "evidence may be isolated that supports virtually any inference one might care to draw." Maj. op. at 74. In the majority's view, "the problem here is one of choosing among the items of evidence," *id.* at 80, and as to the basis employed in such choosing, the majority would simply "defer to the Administrator's judgment." *Id.* at 81. In environmental rule-making, where the record evidence is conflicting and inconclusive, the majority has thus held that the reviewing court must be "highly deferential" toward the agency's decision, *id.* at 68, and affirm that decision if it reflects but minimal rationality. *Id.* at 73.[39] Indeed, as interpreted by two members of the majority (Judges Bazelon and McGowan), a reviewing court must affirm on the basis of procedural regularity alone,

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[37] Dr. Anna M. Baetjer, a member of the National Air Quality Criteria Advisory Committee, critically challenged Respondent's analysis in the health documents, saying: "I think this document lacks scientific, basic sound, scientific knowledge." (A. at 1052). Similarly, Dr. Norton Nelson, a consultant to EPA's Hazardous Materials Advisory Committee, observed: "[W]hat I read here is such a tenuous argument that it becomes, in some degree, self-destroying. And I find it completely deficient." (A. at 998).

[38] A. at 1057; A. at 960; A. at 1936.

[39] Under the minimal rationality standard, as previously explained by Judge Wright, an administrative regulation "can be less than reasonable and still survive the 'arbitrary and capricious' test"; all that is required is that the agency satisfy "only the most rudimentary command of rationality." Wright, *The Courts and the Rule-Making Process: The Limits of Judicial Review,* 59 Cornell L. Rev. 375, 392 (1974).

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without regard to the substantive rationality of the agency's decision (opinion by Bazelon, C.J., at 1-4)—a position Judge Leventhal recognized as advocating "no substantive review at all." Opinion by Leventhal, J., at 1.,

The problem with the majority's suggested standard of review (whether it be Judge Wright's or Chief Judge Bazelon's) is that it virtually immunizes the regulatory agency from substantive accountability, a result totally at odds with the "clear error of judgment" test prescribed by this Court in *Citizens to Preserve Overton Park, Inc.* v. *Volpe,* 401 U.S. 402, 416 (1971), a decision Judge Wright finds "difficult to plumb." Maj. op. at 70 n. 74. Where the evidence is indeed conflicting, the agency would have no difficulty in reciting isolated bits and pieces of inferential support in the record for its position, and thereby establish the minimal rationality the majority says it must affirm. If the majority's analysis is correct, the exercise of judicial review is but a charade.

As the dissent perceived, the question of rationality in administrative rule-making cannot truly be determined by automatically deferring to the agency's judgment in selecting evidence from the record to support its position. Rather, the crucial question to be asked is *why* the agency selected the evidence it did and rejected others.[40] If, in answer to that question, the agency's basis for assessing the evidence is found to be inconsistent and variable according to whether

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[40] In the words of the dissent, "[T]he court concludes that '[t]he problem here is one of choosing among the items of evidence.' We respectfully disagree. The problem here is really one of choosing among the items of evidence *and explaining why!* The Administrator disagreed with the negative conclusions of the Seven Cities study and several other studies, but never said why he disagreed. This is why we *can* fault his conclusion." Dissenting op. at 72 (emphasis in original).

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the particular study supports the agency's position or opposes it, the rule-making can only be characterized as arbitrary and irrational.[41]

With disturbing frequency, the record reveals the use of inconsistent criteria by Respondent in the assessment of evidence. Where a study fails to support a basic premise in Respondent's position, such as, for example, that increased levels of airborne lead correspond to increased blood lead levels,[42] Respondent has rejected the study because of its failure to control dietary sources of lead. In the case of studies supporting Respondent's position, however, the absence of dietary control is forgotten.[43] In response to one of Respondent's more blatant inconsistencies, the dissent remarked:

> "[I]t passes our understanding how anyone can find dietary control a problem in a comparison between greater Philadelphia and greater New York (thus justifying rejection of that data), but of no importance in a comparison between Scarsdale and Harlem (thus justifying reliance on urban-suburban data from greater New York). The art of reconciling total inconsistencies has soared to new heights when this court can seriously conclude (1) that 'dietary lead [can] be assumed relatively constant' between the most affluent

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[41] This Court has recognized that even where evidence exists to support an agency rule, the rule "may nonetheless reflect arbitrary and capricious action." *Bowman Transp., Inc.* v. *Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 284 (1974).

[42] The Seven Cities Study (A. at 840), conducted under the joint sponsorship of EPA and industry, is generally recognized as the most extensive epidemiological study in the field. That study found no significant correlation between airborne lead levels and blood lead levels.

[43] As discovered by the dissent, "the record indicates that *even the studies relied upon by the Administrator failed in this same respect.*" Dissenting op. at 76 (emphasis in original).

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> and the least affluent neighborhoods of greater New York City and (2) that '[t]he Administrator treated *all* the evidence in a consistent and rational manner.' The Administrator has thus utterly failed to present us with a reasoned and principled analysis of the evidence." Dissenting op. at 77-78 (footnotes omitted).

Further, where Respondent fails to provide *any* explanation for its rejection of contrary data, the majority has filled the gap with *post hoc* rationalizations as support for the agency's decision.[44] In so doing, the majority has overstepped its bounds as a *reviewing* court, and has merely accentuated the inadequacies in Respondent's analysis.[45]

In short, the record demonstrates that rather than engaging in the objective, hard look at the evidence that Section 211 contemplates, Respondent has searched high and low for bits and pieces of inferential support for the "get the lead out" crusade that was predetermined by Respondent even before the rule-making process began. In the process, Respondent has functioned as an advocate, not the impartial analyst of the evidence Congress clearly intended. Under the majority's "highly deferential" standard of review, such single minded advocacy on the part of regulatory agencies is wholly endorsed. That expert agencies are entitled to some deference is not disputed, but there must come a point at which the danger signals of arbitrariness are so clear that

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[44] Indeed it is highly significant that the majority, while protesting that a substantive review of the evidence is unnecessary or even improper, devotes 31 pages of its opinion to such a review, in which it undertakes to explain away the shoddy analysis and biased conclusions of the Respondent's "health documents."

[45] "[T]he specific decision must be explained, not merely explainable, in terms of the ingredients announced by the Administrator as comprising the Agency's policies and standards." *Environmental Defense Fund, Inc.* v. *EPA*, 465 F.2d 528, 539 (D.C. Cir. 1972).

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not even "scientific expertise" can shield an agency from judicial intervention.[46]

The record here reveals a classic case of arbitrary rule-making. If such arbitrariness is to be excused in this case, then judicial review has been reduced to an exercise in form only, totally devoid of substance. And when judicial review is gone, there is no protection left against arbitrary procedures, manipulation of data or even political misuse of agency powers.

C. By Sanctioning Regulations Based Principally Upon Preliminary, Untested Data Never Subjected to Scrutiny by the Scientific Community Or Made Available To The Public For Meaningful Comment, The Majority Below Has Frustrated The Policy of The Administrative Procedure Act, And Further Reduced The Due Process Accountability of Administrative Agencies For Their Their Rule-Making Decisions.

Basic to all federal rule-making proceedings is the fundamental due process requirement that the public be advised of the basis of the proposed action and be afforded a meaningful opportunity to comment thereon prior to adoption of the rule. This requirement, expressed in Section 4 of the Administrative Procedure Act,[47] reflects a recognition by Congress of the "essential canons of fairness." *Powhatan Mining Co.* v. *Ickes,* 118 F.2d 105, 109 (6th Cir. 1941).

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[46] *Accord, South Terminal Corp.* v. *EPA,* 504 F.2d 646, 665 (1st Cir. 1974) ("A court would abdicate its function were it, when confronted with important and seemingly plausible objections going to the heart of a key technical determination, to presume that the agency could never behave irrationally"); *Stark* v. *Weinberger,* 497 F.2d 1092, 1099 n. 14 (7th Cir. 1974) (Judicial review requires "more than an uncritical rubber stamping of the administrative action").

[47] 5 U.S.C. § 553.

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The double standard the decision below has established for environmental rule-making is nowhere more pronounced than in the majority's assessment of Respondent's compliance with the notice and opportunity for comment requirements. Public comments on the first two proposals of the regulations (issued in February 1972 and January 1973, respectively), pointed out the fundamental defects in Respondent's position and caused the agency to withdraw each proposal. Under the unreported and unrealistic court order of October, 1973, to reach a final decision in thirty days,[48] however, Respondent issued the regulations and the Third Health Document without the benefit of advance notice or public comment.

Both the preamble to the final regulations and the Third Health Document refer to numerous sources and studies that had never been cited in the previous discredited documents. The Third Health Document contains a total of 190 citations to reference sources. Of that number, a full *151* of them were not cited in the previous health documents. Fifty-two of the references cited bear a date subsequent to November 29, 1972, the date of the second health document, indicating that they were not even in the literature when that review of the evidence was issued.

The significance of the new citations is not so much their numbers, but rather the importance Respondent has assigned to them in defending its position on the final regulations. The dissenting judges have very carefully reviewed the record in this case and have found, almost without exception, that the principal studies relied upon by Respondent were developed after the close of the comment period on the Second Health Document and were cited for the

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[48] *Natural Resources Defense Council* v. *EPA,* D.C. Cir. No. 72-2233; see discussion page 6 *supra.*

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first time in the preamble to the final regulations or the Third Health Document.[49] Critical to Respondent's conclusion that concentrations of lead in the ambient air correlate directly with lead levels in the blood, for example, were two pilot isotope studies,[50] and an unpublished study from Japan.[51] As explained in the preamble to the regulations,[52] data from these studies were "preliminary" only and had "not yet been completely analyzed"; nevertheless, Respondent weighed them against the mass of previous data to the contrary and concluded that an air/blood correlation does exist. As the dissent discovered, these studies did not become available even to Respondent until October and July, respectively, of 1973, and were never mentioned by Respondent as important to its consideration until the final regulations were issued in November, 1973.

Similarly, Respondent has cited a series of studies it calls "persuasive evidence"[53] in support of its hypothesis that children eat dust and dirt contaminated by airborne lead from auto exhausts. As the dissent found, these studies were developed at the last minute, with no opportunity for scrutiny by the general scientific community. A study from Newark, New Jersey, of the effect of lead absorption of proximity to high traffic density, for example, had not even been published at the time the regulations were issued. Dissenting op. at 24. The scientific community thus had no

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[49] See dissenting op. at 17-50, where the dissent first isolates the new studies heavily relied upon by Respondent, and then details their availability (or lack thereof) to petitioners and the public for comment.

[50] R. Doc. No. 113 (A. at 678, 704).

[51] R. Doc. No. 462 (A. at 1092).

[52] 38 Fed. Reg. 33735 (Dec. 6, 1973) (A. at 3).

[53] Third Health Doc. at VI-20 (A. at 130).

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opportunity to determine whether the study had taken into account such important variables as condition of housing, age or ethnic group. Likewise, studies from Chicago, Philadelphia and Rochester which Respondent has termed as "persuasive" did not come to Respondent until *after* the court below had ordered the agency to make a decision within thirty days and shortly before the regulations were issued. Dissenting op. at 25. Again, no opportunity for public comment on these critical studies was afforded.

The majority below considers this objection to Respondent's procedure unimportant, stating that the agency had invited and received public comment on the lead phasedown proposal on three previous occasions. Maj. op. at 99. What the majority refuses to recognize, however, is that the basic documents upon which Respondent ultimately relied in defending its position were effectively shielded from public scrutiny by the timing of the court's order and issuance of the regulations. As the dissent noted:

> "[B]y October-November 1973 he [the Administrator] was largely shifting his ground from the discredited scientific data of the First and Second Health Documents to *new* data embraced in the Third Health Document. This is the crucial time at which informed comment from the best scientific minds in other government agencies and elsewhere should have been sought —unless EPA was irrevocably resolved to promulgate the restrictive regulations on lead which it had originally proposed years before, in spite of the barrage of unanimous critical comment from other government scientific minds, as well as interested outsiders." Dissenting op. 26-27.

Concerning the prior opportunities for comment, the dissent recognized:

> "It certainly, as a practical matter does no good for an agency to propose an action, support it with data which is severely criticized, abandon that data for new, fail to subject the new data to informed comment, and then promulgate the same proposed regulations on the basis of new data." Dissenting op. at 38.

The majority further suggests that the notice and opportunity for comment requirements of the Administrative Procedure Act were fully satisfied when all the studies and documents referred to in the preamble and the Third Health Document were placed in the agency's public information file, Maj. op. at 100 & n. 102, and that in any event Petitioner can have no complaint because it was furnished all the record documents as a result of a Freedom of Information Act suit. Maj. op. at 108 n. 118. The absurdity of this position is obvious. As observed by the dissent:

> "[I]t is not enough under the Administrative Procedure Act merely to make the scientific data 'available' to the public and all interested parties. *First,* the claimed 'availability' here boils down to a compelled furnishing of data to *one* interested party under the Freedom of Information Act and the placing of hundreds of miscellaneous documents—scientific studies, papers, published articles, etc.—in a poorly indexed dust bin of a file in the public rooms of the Environmental Protection Agency. *Second,* there was *never any notice*—and our colleagues do not and can not contend that there was—*on which data* out of the great miscellaney EPA *would rely* until the Third Health Document was published simultaneously with the regulations. *Third,* the opportunity to comment effectively on the new data on which EPA ultimately relied was farcical, as our detailed discussion above nails down." Dissenting op. at 46-47 (emphasis in original).

The procedural irregularities sanctioned below have serious implications for future regulatory actions. The majority opinion blithely ignores (and indeed discounts by its overly deferential approach) the growing public clamor for independent research bodies to advise the regulatory agencies on highly complex technical issues like this (as was done in the recent restructuring of the Atomic Energy Commission). The majority fails to take into account its own unrealistic time limitation placed on the Respondent that made it impossible for public comment to be solicited with respect to the final regulations.[54] Finally, the majority puts its stamp of approval on a procedure whereby an agency avoids the public notice and comment requirements Congress has imposed by simply dumping thousands of pages of record material into a public information file (without proper indices or classifications)—a procedure totally repugnant to traditional concepts of principled administrative rule-making.[55] As the dissent perceived, "From the pages of the court's opinion there seeps the theme that this is an environmental case; hence, the court like the agency need not labor by the usual rules." Dissenting op. at 50. In order to assure the public the "most intelligent, optimally beneficial decision" possible,[56] however, environmental agencies

[54] It is perhaps of considerable importance that Judge Wright, who wrote two lengthy opinions in this case to justify all the Respondent's actions, was the leading member of the panel that put the Respondent under an unrealistic 30 day deadline to take final action against lead antiknocks.

[55] Judges Bazelon and McGowan, in their concurring opinion, likewise lamented the procedural inadequacies of Respondent's rulemaking, observing that "Ordinarily . . . I think a record which so burdens judicial review would require a remand for clarification." Op. by Bazelon, C.J., at 5. Indeed, a total of six judges of the court below found significant irregularities in Respondent's procedures.

[56] *Calvert Cliffs' Coord. Comm., Inc.* v. *AEC,* 449 F.2d 1109, 1114 (D.C. Cir. 1971).

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can be no less accountable for their decisions than are other administrative bodies.

The actions of the administrative agency in this case are so difficult to justify that the majority below first had to go to extremes to supply even "minimal rationality," and then had to be overly deferential to so-called administrative expertise to reach its final result. In so doing, the majority has notified the Respondent that henceforth there will be no meaningful judicial review of environmental regulations. This will likely encourage the disregard of statutory standards, the performance of shoddy scientific analysis and even the manipulation of data, and the avoidance of rules designed to give the public advance notice and a meaningful opportunity to comment on proposed regulations. Such a momentous redefinition of the scope of judicial review in the vitally important area of environmental controls requires prompt review by this Court.

CONCLUSION

For these reasons, a writ of certiorari should issue to review the judgment and opinion of the Court of Appeals for the District of Columbia Circuit.

Respectfully submitted,

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May 5, 1976

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CERTIFICATE OF SERVICE

I, John J. Adams, counsel for the Petitioner, and a member of the Bar of the Supreme Court of the United States, hereby certify that I have served all parties required to be served by depositing three copies of the foregoing Petition for Writ of Certiorari in the United States Mail, first class postage prepaid, this 5th day of May, 1976, addressed to: The Solicitor General, Department of Justice, Washington, D. C., and to Robert V. Zener, Environmental Protection Agency, Waterside Mall Building, 4th and M Streets, S.W., Washington, D. C. 20460.

JOHN J. ADAMS
Counsel for Petitioner

APPENDIX A

Clean Air Act
42 U.S.C. §§ 1857c-3, 1857c-4, 1857f-1, 1857f-6c

Administrative Procedure Act
5 U.S.C. § 553

Environmental Protection Agency Regulations
40 C.F.R. §§ 80.1, 80.2, 80.20, 80.25, 80.26

42 U.S.C. § 1857c-3

Air Quality Criteria And Control Techniques

Sec. 108. (a)(1) For the purpose of establishing national primary and secondary ambient air quality standards, the Administrator shall within 30 days after the date of enactment of the Clean Air Amendments of 1970 publish, and shall from time to time thereafter revise, a list which includes each air pollutant—

(A) which in his judgment has an adverse effect on public health or welfare;

(B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and

(C) for which air quality criteria had not been issued before the date of enactment of the Clean Air Amendments of 1970, but for which he plans to issue air quality criteria under this section.

(2) The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the

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ambient air in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on—

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare.

(b)(1) Simultaneously with the issuance of criteria under subsection (a), the Administrator shall, after consultation with appropriate advisory committees and Federal departments and agencies, issue to the States and appropriate air pollution control agencies information on air pollution control techniques, which information shall include data relating to the technology and costs of emission control. Such information shall include such data as are available on available technology and alternative methods of prevention and control of air pollution. Such information shall also include data on alternative fuels, processes, and operating methods which will result in elimination or significant reduction of emissions.

(2) In order to assist in the development of information on pollution control techniques, the Administrator may establish a standing consulting committee for each air pollutant included in a list published pursuant to subsection (a)(1), which shall be comprised of technically qualified individuals representative of State and local governments, industry, and the academic community. Each such com-

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mittee shall submit as appropriate, to the Administrator information related to that required by paragraph (1).

(c) The Administrator shall from time to time review, and, as appropriate, modify, and reissue any criteria or information on control techniques issued pursuant to this section.

(d) The issuance of air quality criteria and information on air pollution control techniques shall be announced in the Federal Register and copies shall be made available to the general public.

42 U.S.C. § 1857c-4

National Ambient Air Quality Standards

Sec. 109. (a) (1) The Administrator—

(A) within 30 days after the date of enactment of the Clean Air Amendments of 1970, shall publish proposed regulations prescribing a national primary ambient air quality standard and a national secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued prior to such date of enactment; and

(B) after a reasonable time for interested persons to submit written comments thereon (but no later than 90 days after the initial publication of such proposed standards) shall by regulation promulgate such proposed national primary and secondary ambient air quality standards with such modifications as he deems appropriate.

(2) With respect to any air pollutant for which air quality criteria are issued after the date of enactment of the Clean Air Amendments of 1970, the Administrator shall publish, simultaneously with the issuance of such criteria

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and information, proposed national primary and secondary ambient air quality standards for any such pollutant. The procedure provided for in paragraph (1)(B) of this subsection shall apply to the promulgation of such standards.

(b)(1) National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed under subsection (a) shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

42 U.S.C. § 1857f-1

Sec. 202. (a) Except as otherwise provided in subsection (b)—

(1) The Administrator shall by regulation prescribe (and from time to time revise) in accordance with the provisions of this section, standards applicable to the emission of any air pollutant from any class or classes of new motor vehicles or new motor vehicle engines, which in his judgment causes or contributes to, or is likely to cause or to contribute to, air pollution which endangers the public health or welfare. Such standards shall be applicable to such vehicles and engines for their useful life (as determined under subsection (d)),

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whether such vehicles and engines are designed as complete systems or incorporate devices to prevent or control such pollution.

(2) Any regulation prescribed under this subsection (and any revision thereof) shall take effect after such period as the Administrator finds necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period.

(b)(1)(A) The regulations under subsection (a) applicable to emissions of carbon monoxide and hydrocarbons from light duty vehicles and engines manufactured during or after model year 1977 shall contain standards which require a reduction of at least 90 per centum from emissions of carbon monoxide and hydrocarbons allowable under the standards under this section applicable to light duty vehicles and engines manufactured in model year 1970.

The regulations under subsection (a) applicable to emissions of carbon monoxide and hydrocarbons from light-duty vehicles and engines manufactured during model years 1975 and 1976 shall contain standards which are identical to the interim standards which were prescribed (as of December 1, 1973) under paragraph (5)(A) of this subsection for light-duty vehicles and engines manufactured during model year 1975.

(B) The regulations under subsection (a) applicable to emissions of oxides of nitrogen from light duty vehicles and engines manufactured during or after model year 1978 shall contain standards which require a reduction of at least 90 per centum from the average of emissions of oxides of nitrogen actually measured from light duty vehicles manufactured during model year 1971 which are not subject to

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any Federal or State emission standard for oxides of nitrogen. Such average of emissions shall be determined by the Administrator on the basis of measurements made by him.

The regulations under subsection (a) applicable to emissions of oxides of nitrogen from light-duty vehicles and engines manufactured during model years 1975 and 1976 shall contain standards which are identical to the standards which were prescribed (as of December 1, 1973) under subsection (a) for light-duty, vehicles and engines manufactured during model year 1975. The regulations under subsection (a) applicable to emissions of oxides of nitrogen from light-duty vehicles and engines manufactured during model year 1977 shall contain standards which provide that such emissions from such vehicles and engines may not exceed 2.0 grams per vehicle mile.

(2) Emission standards under paragraph (1), and measurement techniques on which such standards are based (if not promulgated prior to the date of enactment of the Clean Air Amendments of 1970), shall be prescribed by regulation within 180 days after such date.

(3) For purposes of this part

(A)(i) The term 'model year' with reference to any specific calendar year means the manufacturer's annual production period (as determined by the Administrator), which includes January 1 of such calendar year. If the manufacturer has no annual production period, the term 'model year' shall mean the calendar year.

(ii) For the purpose of assuring that vehicles and engines manufactured before the beginning of a model year were not manufactured for purposes of circumventing the effective date of a standard required to be prescribed by subsection (b), the Administrator may prescribe regulations

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defining 'model year' otherwise than as provided in clause (i).

(B) The term 'light duty vehicles and engines' means new light duty motor vehicles and new light duty motor vehicle engines, as determined under regulations of the Administrator.

(4) On July 1 of 1971, and of each year thereafter, the Administrator shall report to the Congress with respect to the development of systems necessary to implement the emission standards established pursuant to this section. Such reports shall include information regarding the continuing effects of such air pollutants subject to standards under this section on the public health and welfare, the extent and progress of efforts being made to develop the necessary systems, the costs associated with development and application of such systems, and following such hearings as he may deem advisable, any recommendations for additional congressional action necessary to achieve the purposes of this Act. In gathering information for the purposes of this paragraph and in connection with any hearing, the provisions of section 307 (a) (relating to subpoenas) shall apply.

(5)(A) At any time after January 1, 1975, any manufacturer may file with the administrator an application requesting the suspension for one year only of the effective date of any emission standard required by paragraph (1)(A) with respect to such manufacturer for light-duty vehicles and engines manufactured in model year 1977. The Administrator shall make his determination with respect to any such application within sixty days. If he determines, in accordance with the provisions of this subsection, that such suspension should be granted, he shall simultaneously with such determination prescribe by regulation

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interim emission standards which shall apply (in lieu of the standards required to be prescribed by paragraph (1)(A) of this subsection) to emissions of carbon monoxide or hydrocarbons (or both) from such vehicles and engines manufactured during model year 1977.

(B) Any interim standards prescribed under this paragraph shall reflect the greatest degree of emission control which is achievable by application of technology which the Administrator determines is available, giving appropriate consideration to the cost of applying such technology within the period of time available to manufacturers.

(C) Within 60 days after receipt of the application for any such suspension, and after public hearing, the Administrator shall issue a decision granting or refusing such suspension. The Administrator shall grant such suspension only if he determine that (i) such suspension is essential to the public interest or the public health and welfare of the United States, (ii) all good faith efforts have been made to meet the standards established by this subsection, (iii) the applicant has established that effective control technology, processes, operating methods, or other alternatives are not available or have not been available for a sufficient period of time to achieve compliance prior to the effective date of such standards, and (iv) the study and investigation of the National Academy of Sciences conducted pursuant to subsection (c) and other information available to him has not indicated that technology, processes, or other alternatives are available to meet such standards.

(D) Nothing in this paragraph shall extend the effective date of any emission standard required to be prescribed under this subsection for more than one year.

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(c)(1) The Administrator shall undertake to enter into appropriate arrangements with the National Academy of Sciences to conduct a comprehensive study and investigation of the technology feasibility of meeting the emissions standards required to be prescribed by the Administrator by subsection (b) of this section.

(2) Of the funds authorized to be appropriated to the Administrator by this Act, such amounts as are required shall be available to carry out the study and investigation authorized by paragraph (1) of this subsection.

(3) In entering into any arrangement with the National Academy of Sciences for conducting the study and investigation authorized by paragraph (1) of this subsection, the Administrator shall request the National Academy of Sciences to submit semiannual reports on the progress of its study and investigation to the Administrator and the Congress, beginning not later than July 1, 1971, and continuing until such study and investigation is completed.

(4) The Administrator shall furnish to such Academy at its request any information which the Academy deems necessary for the purpose of conducting the investigation and study authorized by paragraph (1) of this subsection. For the purpose of furnishing such information, the Administrator may use any authority he has under this Act (A) to obtain information from any person, and (B) to require such person to conduct such tests, keep such records, and make such reports respecting research or other activities conducted by such person as may be reasonably necessary to carry out this subsection.

(d) The Administrator shall prescribe regulations under which the useful life of vehicles and engines shall be determined for purposes of subsection (a)(1) of this section and

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section 207. Such regulations shall provide that useful life shall—

(1) in the case of light duty vehicles and light duty vehicle engines, be a period of use of five years or of fifty thousand miles (or the equivalent), whichever first occurs; and

(2) in the case of any other motor vehicle or motor vehicle engine, be a period of use set forth in paragraph (1) unless the Administrator determines that a period of use of greater duration or mileage is appropriate.

(e) In the event a new power source or propulsion system for new motor vehicles or new motor vehicle engines is submitted for certification pursuant to section 206(a), the Administrator may postpone certification until he has prescribed standards for any air pollutants emitted by such vehicle or engine which cause or contribute to, or are likely to cause or contribute to, air pollution which endangers the public health or welfare but for which standards have not been prescribed under subsection (a).

42 U.S.C. § 1857f-6c

Regulations Of Fuels

Sec. 211. (a) The Administrator may by regulation designate any fuel or fuel additive and, after such date or dates as may be prescribed by him, no manufacturer or processor of any such fuel or additive may sell, offer for sale, or introduce into commerce such fuel or additive unless the Administrator has registered such fuel or additive in accordance with subsection (b) of this section.

(b)(1) For the purpose of registration of fuels and fuel additives, the Administrator shall require—

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"(A) the manufacturer of any fuel to notify him as to the commercial identifying name and manufacturer of any additive contained in such fuel; the range of concentration of any additive in the fuel; and the purpose-in-use of any such additive; and

(B) the manufacturer of any additive to notify him as to the chemical composition of such additive.

(2) For the purpose of registration of fuels and fuel additives, the Administrator may also require the manufacturer of any fuel or fuel additive—

(A) to conduct tests to determine potential public health effects of such fuel or additive (including, but not limited to, carcinogenic, teratogenic, or mutagenic effects), and

(B) to furnish the description of any analytical technique that can be used to detect and measure any additive in such fuel, the recommended range of concentration of such additive, and the recommended purpose-in-use of such additive, and such other information as is reasonable and necessary to determine the emissions resulting from the use of the fuel or additive contained in such fuel, the effect of such fuel or additive on the emission control performance of any vehicle or vehicle engine, or the extent to which such emissions affect the public health or welfare.

Tests under subparagraph (A) shall be conducted in conformity with test procedures and protocols established by the Administrator. The result of such tests shall not be considered confidential.

(3) Upon compliance with the provisions of this subsection, including assurances that the Administrator will receive changes in the information required, the Administrator shall register such fuel or fuel additive.

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(c)(1) The Administrator may, from time to time on the basis of information obtained under subsection (b) of this section or other information available to him, by regulation, control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel additive for use in a motor vehicle or motor vehicle engine (A) if any emission products or such fuel or fuel additive will endanger the public health or welfare, or (B) if emission products of such fuel or fuel additive will impair to a significant degree the performance of any emission control device or system which is in general use, or which the Administrator finds has been developed to a point where in a reasonable time it would be in general use were such regulation to be promulgated.

(2)(A) No fuel, class of fuels, or fuel additive may be controlled or prohibited by the Administrator pursuant to clause (A) of paragraph (1) except after consideration of all relevant medical and scientific evidence available to him, including consideration of other technologically or economically feasible means of achieving emission standards under section 202.

(B) No fuel or fuel additive may be controlled or prohibited by the Administrator pursuant to clause (B) of paragraph (1) except after consideration of available scientific and economic data, including a cost benefit analysis comparing emission control devices or systems which are or will be in general use and require the proposed control or prohibition with emission control devices or systems which are or will be in general use and do not require the proposed control or prohibition. On request of a manufacturer of motor vehicles, motor vehicle engines, fuels, or fuel additives submitted within 10 days of notice of proposed rulemaking, the Administrator shall hold a public hearing and publish his findings with respect to any matter he is re-

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quired to consider under this subparagraph. Such findings shall be published at the time of promulgation of final regulations.

(C) No fuel or fuel additive may be prohibited by the Administrator under paragraph (1) unless he finds, and publishes such finding, that in his judgment such prohibition will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited.

(3)(A) For the purpose of obtaining evidence and data to carry out paragraph (2), the Administrator may require the manufacturer of any motor vehicle engine to furnish any information which has been developed concerning the emissions from motor vehicles resulting from the use of any fuel additive, or the effect of such use on the performance of any emission control device or system.

(B) In obtaining information under subparagraph (A), section 307(a) (relating to subpoenas) shall be applicable.

(4)(A) Except as otherwise provided in subparagraph (B) or (C), no State (or political subdivision thereof) may prescribe or attempt to enforce, for purposes of motor vehicle emission control, any control or prohibition respecting use of a fuel or fuel additive in a motor vehicle or motor vehicle engine—

(i) if the Administrator has found that no control or prohibition under paragraph (1) is necessary and has published his finding in the Federal Register, or

(ii) if the Administrator has prescribed under paragraph (1) a control or prohibition applicable to such fuel or fuel additive, unless State prohibition or control is identical to

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the prohibition or control prescribed by the Administrator.

(B) Any State for which application of section 209(a) has at anytime been waived under section 209(b) may at any time prescribe and enforce, for the purpose of motor vehicle emission control, a control or prohibition respecting any fuel or fuel additive.

(C) A State may prescribe and enforce, for the purposes of motor vehicle emission control, a control or prohibition respecting the use of a fuel or fuel additive in a motor vehicle or motor vehicle engine if an applicable implementation plan for such State under section 110 so provides. The Administrator may approve such provision in an implementation plan, or promulgate an implementation plan containing such a provision, only if he finds that the State control or prohibition is necessary to achieve the national primary or secondary ambient air quality standard which the plan implements.

(d) Any person who violates subsection (a) or the regulations prescribed under subsection (c) or who fails to furnish any information required by the Administrator under subsection (b) shall forfeit and pay to the United States a civil penalty of $10,000 for each and every day of the continuance of such violation, which shall accrue to the United States and be recovered in a civil suit in the name of the United States, brought in the district where such person has his principal office or in any district in which he does business. The Administrator may, upon application therefor, remit or mitigate any forfeiture provided for in this subsection and he shall have authority to determine the facts upon all such applications.

5 U.S.C. § 553

§ 553. *Rule making.*

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, Sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

40 C.F.R. §§ 80.1, 80.2, 80.20, 80.25, 80.26

Part 80 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

1. In § 80.1, the second sentence is revised to read as follows:

§ 80.1 *Scope.*

* * * These regulations are based upon a determination by the Administrator that the emission product of a fuel or additive will endanger the public health, or will im-

pair to a significant degree the performance of a motor vehicle emission control device in general use or which the Administrator finds has been developed to a point where in a reasonable time it would be in general use were such regulations promulgated; and certain other findings specified by the Act.

2. In § 80.2, a new paragraph (m) is added as follows:

§ 80.2 *Definitions.*

* * *

(m) "Lead additive manufacturer" means any person who produces a lead additive or sells a lead additive under his own name.

3. A new § 80.20 is added as follows:

§ 80.20 *Controls applicable to gasoline refiners.*

(a)(1) In the manufacture of gasoline at any refinery, no gasoline refiner shall exceed the average lead content per gallon specified below for each 3-month period (January through March, April through June, July through September, October through December):

(i) 1.7 grams of lead per gallon, after January 1, 1975;

(ii) 1.4 grams of lead per gallon, after January 1, 1976;

(iii) 1.0 grams of lead per gallon, after January 1, 1977;

(iv) 0.8 grams of lead per gallon, after January 1, 1978;

(v) 0.5 grams of lead per gallon, after January 1, 1979.

(2) For each 3-month period (January through March, April through June, July through September, October through December) the average lead content per gallon

shall be computed by dividing total grams of lead used at a refinery in the manufacture of gasoline by total gallons of gasoline manufactured at such refinery.

(3) For each 3-month period (January through March, April through June, July through September, October through December) commencing with the period January 1, 1975 through March 31, 1975, each refiner shall submit to the Administrator a report showing for each refinery (i) the total grams of lead in lead additive inventory on the first day of the period, (ii) the total grams of lead received during the period, (iii) the total grams of lead in lead additive inventory on the last day of the period, (iv) the total gallons of gasoline produced by such refinery during the period, and (v) the average lead content in each gallon of gasoline produced during the period. Reports shall be submitted within 15 days after the close of the reporting period, on forms supplied by the Administrator upon request.

(b) The provisions of paragraph (a)(1)(i) and (ii) of this section shall not be applicable to any refiner which does not have more than 30,000 barrels per day crude oil or bona fide feed stock capacity from owned or leased facilities or from facilities made available to such refiner under an arrangement such as, but not limited to, an exchange agreement (except one on a refined product for refined product basis) or a through-put or other form of processing agreement, with the same effects as though such facilities had been leased.

4. A new § 80.25 is added as follows:

§ 80.25 *Controls applicable to lead additive manufacturers.*

For each 3-month period (January through March, April through June, July through September, October through

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December) commencing with the period January 1, 1975 through March 31, 1975, each lead additive manufacturer shall submit to the Administrator a report showing the total grams of lead shipped to each refinery by such lead additive manufacturer during the period. Reports shall be submitted within 15 days after the close of the reporting period, on forms supplied by the Administrator upon request.

5. A new § 80.26 is added as follows:

§ 80.26 *Confidentiality of information.*

Information obtained by the Administrator or his representatives pursuant to this part shall be treated, insofar as its confidentiality is concerned, in accordance with the provisions of 40 CFR Part 2.

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MICHAEL RODAK, JR.,

Nos. 75-1602

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

ETHYL CORPORATION, *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY, *Respondent*

PPG INDUSTRIES, INC., *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY, *Respondent*

E. I. DU PONT DE NEMOURS AND COMPANY, *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY, *Respondent*

NALCO CHEMICAL COMPANY, *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY, *Respondent*

NATIONAL PETROLEUM REFINERS ASSOCIATION, *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY, *Respondent*

JOINT APPENDIX TO PETITIONS FOR WRIT OF CERTIORARI

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United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 73-2205

ETHYL CORPORATION, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 73-2268

PPG INDUSTRIES, INC., PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 73-2269

E. I. DUPONT DE NEMOURS & COMPANY, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

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No. 73-2270

NALCO CHEMICAL COMPANY, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 74-1021

NATIONAL PETROLEUM REFINERS ASSOCIATION, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

Petitions for Review of an Order of the
Environmental Protection Agency

On Rehearing *En Banc*

Argued *En Banc* May 30, 1975

Decided March 19, 1976

SYLLABUS

Section 211(c)(1)(A) of the Clean Air Act authorizes the Administrator of the Environmental Protection Agency to regulate gasoline additives whose emission products "will endanger the public health or welfare * * *." 42 U.S.C. § 1857f-6c(c)(1)(A) (1970). Acting pur-

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suant to that power in rule-making proceedings, the Administrator determined that leaded gasoline automotive emissions present "a significant risk of harm" to the public health, thereby endangering it within the contemplation of the statute. Based on this finding, the Administrator issued regulations requiring annual reductions in the lead content of leaded gasoline. *Held*:

1. The Administrator's interpretation of the statutory "will endanger" standard is entitled to great deference. *Train* v. *Natural Resources Defense Council, Inc.*, 421 U.S. 60, 75 (1975). We find no basis in the language of the statute or in its legislative history to fault his interpretation. In applying the "will endanger" standard, the Administrator is authorized to assess risks of harm and, where the risk is found to be significant, to act to prevent the harm from happening. Thus the regulatory action under this precautionary statute should precede, and hopefully prevent, the perceived harm. Pp. 17-66.

a. Some of the questions involved in promulgation of environmental regulations "are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analyses." *Industrial Union Department, AFL-CIO* v. *Hodgson*, 162 U.S.App.D.C. 331, 338, 499 F.2d 467, 474 (1974). Pp. 45-56.

b. In making his policy judgment by assessing risks the Administrator is not required to limit his consideration to the danger presented by lead additives "in and of themselves." He may consider the cumulative impact of lead additives with other sources of human exposure to lead. Pp. 56-61.

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2. The Administrator's determination that lead emissions "present a significant risk of harm to the health of urban populations, particularly to the health of city children," is not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law * * *." 5 U.S.C. § 706(2)(A) (1970). His determination has a rational basis in the evidence. Pp. 66-97.

a. We must look at the Administrator's decision not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agency action to certain minimal standards of rationality. Pp. 66-74.

b. We need not seek a single dispositive scientific study that fully supports the Administrator's determination. Science does not work that way; nor does agency fact-finding. Rather, the Administrator's decision may be fully supportable if it is based, as it is here, on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is often cumulative; the more supporting, albeit inconclusive, evidence available, the more likely the accuracy of the conclusion. Pp. 75-76.

c. The vast bulk of the evidence before the Administrator provides inferences, no one of which is dispositive, which support the Administrator's findings. Particularly in light of the precautionary nature of the "will endanger" standard, we cannot find the Administrator's conclusion that lead automotive emissions present a significant risk of harm to the public health arbitrary or capricious. Pp. 77-97.

The order of the Environmental Protection Agency is

Affirmed.

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Joseph C. Carter, Jr., with whom *John J. Adams* and *David F. Peters* were on the brief, for petitioner in No. 73-2205. *Arnold H. Quint* also entered an appearance for petitioner in No. 73-2205.

Daniel M. Gribbon, with whom *Allan J. Topol* and *Charles Lister* were on the brief, for petitioners in Nos. 73-2268 and 73-2269.

Victor P. Kayser, with whom *John C. Berghoff, Jr.*, *Robert E. Nord*, *David Machanic*, and *William H. Fitz* were on the brief, for petitioner in No. 73-2270.

H. Edward Dunkelberger, Jr., with whom *Theodore L. Garrett* was on the brief, for petitioner in No. 74-1021.

Robert V. Zener, General Counsel, Environmental Protection Agency, and *Leslie A. Carothers*, Attorney, Environmental Protection Agency, with whom *Wallace H. Johnson*, Assistant Attorney General, and *Edmund B. Clark*, *Martin Green*, and *Edward J. Shawaker*, Attorneys, Department of Justice, were on the brief, for respondent. *Raymond N. Zagone*, Attorney, Department of Justice, also entered an appearance for respondent in No. 73-2268.

David Schoenbrod filed a brief on behalf of Natural Resources Defense Council, Inc. *et al.* as *amici curiae* urging affirmance.

Before BAZELON, *Chief Judge*, and WRIGHT, MCGOWAN, TAMM, LEVENTHAL, ROBINSON, MACKINNON, ROBB, and WILKEY, *Circuit Judges*, sitting *en banc*.

Opinion for the court, in which *Chief Judge* BAZELON and *Circuit Judges* MCGOWAN, LEVENTHAL, and ROBINSON concur, filed by *Circuit Judge* WRIGHT.

Concurring opinion, in which *Circuit Judge* MCGOWAN joins, filed by *Chief Judge* BAZELON.

Concurring statement filed by *Circuit Judge* LEVENTHAL.

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Dissenting opinion filed by *Circuit Judge* MACKINNON.

Dissenting opinion, in which *Circuit Judges* TAMM and ROBB join, filed by *Circuit Judge* WILKEY.

WRIGHT, *Circuit Judge*: Man's ability to alter his environment has developed far more rapidly than his ability to foresee with certainty the effects of his alterations. It is only recently that we have begun to appreciate the danger posed by unregulated modification of the world around us, and have created watchdog agencies whose task it is to warn us, and protect us, when technological "advances" present dangers unappreciated—or unrevealed—by their supporters. Such agencies, unequipped with crystal balls and unable to read the future, are nonetheless charged with evaluating the effects of unprecedented environmental modifications, often made on a massive scale. Necessarily, they must deal with predictions and uncertainty, with developing evidence, with conflicting evidence, and, sometimes, with little or no evidence at all. Today we address the scope of the power delegated one such watchdog, the Environmental Protection Agency (EPA). We must determine the certainty required by the Clean Air Act before EPA may act to protect the health of our populace from the lead particulate emissions of automobiles.

Section 211(c)(1)(A) of the Clean Air Act[1] authorizes the Administrator of EPA to regulate gasoline additives whose emission products "will endanger the public health or welfare * * *." 42 U.S.C. § 1857f-6c(c)(1)(A). Acting pursuant to that power, the Administrator, after notice and comment, determined that the automotive emissions caused by leaded gasoline present "a signi-

[1] All sections of the Act pertinent to this case were added by the Clean Air Amendments of 1970, Pub. L. 91-604, Dec. 31, 1970, 84 Stat. 1698-1700.

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ficant risk of harm" to the public health. Accordingly, he promulgated regulations that reduce, in step-wise fashion, the lead content of leaded gasoline.[2] We must decide whether the Administrator properly interpreted the meaning of Section 211(c)(1)(A) and the scope of his power thereunder, and, if so, whether the evidence adduced at the rule-making proceeding supports his final determination. Finding in favor of the Administrator on both grounds, and on all other grounds raised by petitioners, we affirm his determination.

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[2] The new regulations, together with regulations requiring all gasoline refiners to market at least one line of lead-free gasoline, are set out in 40 C.F.R. § 80 (1975). The lead-free regulations serve a different purpose than the low-lead regulations now before us. Leaded gasoline fouls the catalytic converter emission control system developed by the major automobile companies to meet the air pollutant emission standards set by Congress in § 202 of the Clean Air Act. 42 U.S.C. § 1857f-1. So as to allow implementation of the catalytic converter, the Administrator ordered the marketing of lead-free gasoline pursuant to his authority under § 211(c)(1)(B), the sister section to § 211(c)(1)(A) at issue here. Section 211(c)(1)(B) gives EPA authority to regulate gasoline additives whose emission products "will impair to a significant degree the performance of any emission control device or system which is in general use * * *." 42 U.S.C. § 1857f-6c(c)(1)(B). The lead-free regulations were approved by this court in *Amoco Oil Co.* v. *EPA*, 163 U.S.App.D.C. 162, 501 F.2d 722 (1974).

On March 5, 1975, the Administrator suspended the 1977 statutory standards for automobile emissions of hydrocarbons and carbon monoxide, establishing interim standards for that model year equal to those now in effect. 40 FED. REG. 11900. This action was taken to slow the emission reduction schedule and thereby minimize a potential health hazard posed by the gradual increase in sulfuric acid emissions produced by the catalytic converter. So far as this decision is relevant to this case, it bears noting that the lead-free gasoline regulations will continue in effect and automobiles will continue to be equipped with catalytic converters for the foreseeable future. *See* note 68 *infra*.

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I. The Facts, the Statute, the Proceedings and the Regulations

Hard on the introduction of the first gasoline-powered automobiles came the discovery that lead "antiknock" compounds, when added to gasoline, dramatically increase the fuel's octane rating. Increased octane allows for higher compression engines, which operate with greater efficiency. Since 1923 antiknocks have been regularly added to gasoline, and a large industry has developed to supply those compounds. Today, approximately 90 percent of motor gasoline manufactured in the United States contains lead additives, even though most 1975 and 1976 model automobiles are equipped with catalytic converters, which require lead-free gasoline. From the beginning, however, scientists have questioned whether the addition of lead to gasoline, and its consequent diffusion into the atmosphere from the automobile emission, poses a danger to the public health.[3] As use of automobiles,

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[3] The principal studies and symposia over the years on the subject have included Sayers *et al.*, "Experimental Studies on the Effect of Ethyl Gasoline and Its Combustion Products," Bureau of Mines, 1927; HEW, "Public Health Aspects of Increasing Tetraethyl Lead Content in Motor Fuel," Public Health Service Pub. No. 712, 1959; Kehoe, "The Metabolism of Lead in Man in Health and Disease," The Harben Lectures, 1960, JA 500-579; HEW, "Survey of Lead in the Atmosphere of Three Urban Communities," JA 789-839; HEW, "Symposium on Environmental Lead Contamination," Public Health Service Pub. No. 1440, 1966, JA 975-984; Tepper & Levin, "A Survey of Air and Population Lead Levels in Selected American Communities," 1972, JA 840-916; National Academy of Sciences, "Airborne Lead in Perspective," 1972, JA 309-362; EPA and Commission of European Communities, Proceedings of International Symposium, "Environmental Health Aspects of Lead," Luxembourg, 1973, JA 676-677; EPA and National Institute of Environmental Health Services, Conference on "Low-Level Lead Toxicity," Raleigh, N.C., 1973.

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and emission of lead particulates, has accelerated in the last quarter century, this concern has mounted. The reasons for concern are obvious (and essentially undisputed by petitioners): (1) lead in high concentrations in the body is toxic; (2) lead can be absorbed into the body from the ambient air; and (3) lead particulate emissions from gasoline engines account for approximately 90 percent of the lead in our air. Despite these apparent reasons for concern, hard proof of any danger caused by lead automotive emissions has been hard to come by. Part of the reason for this lies in the multiple sources of human exposure to lead.

Lead is an ubiquitous element. It is found in the land, in the sea, in plants, in animals, and, ultimately, in humans. Traces of lead ranging from 10 to 40 micrograms per 100 grams of blood (10-40 ug/100g) [4] are found in everyone, including those living in environments with almost no atmospheric lead. NATIONAL ACADEMY OF SCIENCES COMMITTEE ON BIOLOGIC EFFECTS OF ATMOSPHERIC POLLUTANTS, AIRBORNE LEAD IN PERSPECTIVE 118 (1972) (hereinafter NAS Report). Despite its universal presence, however, lead serves no known purpose in the human body, and at higher concentrations is toxic, causing anemia, severe intestinal cramps, paralysis of nerves, fatigue, and even death. Clinical symptoms of lead poisoning appear at blood lead levels of 80-100 ug or higher, and symptomatic lead poisoning may appear at levels of 50-60 ug, particularly in the

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[4] Some of the data discussed herein speak of micrograms of lead per 100 *grams* of blood, while other data report micrograms per 100 *milliliters* of blood. Since the density of blood is close to 1.0, these figures are directly comparable. Therefore, lead concentrations, unless otherwise indicated, will hereafter simply be given in micrograms. *See* NATIONAL ACADEMY OF SCIENCES COMMITTEE ON BIOLOGIC EFFECTS OF ATMOSPHERIC POLLUTANTS, AIRBORNE LEAD IN PERSPECTIVE 61 n. * (1972) (hereinafter NAS Report).

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presence of anemia. EPA's POSITION ON THE HEALTH IMPLICATIONS OF AIRBORNE LEAD (hereinafter Third Health Document) at III-1, Joint Appendix (hereinafter JA) 54-55.

Human body lead comes from three major sources. In most people, the largest source is the diet. EPA estimates daily dietary lead intake for adults to average 200-300 ug per day, with a range of 100-500 ug a day. Third Health Document at V-2, JA 82. Absorption of dietary lead into the bloodstream is estimated at about 10 percent, although in children absorption may be as high as 50 percent. Thus the average adult adds 20-30 ug of lead to his bloodstream daily from his diet alone. This daily intake, which may be highly variable depending on individual diets, NAS Report at 50, is generally regarded as, for all practical purposes, uncontrollable.[5]

A second major source of the body's lead burden, at least among urban children, *is* regarded as controllable, although effective control may be both difficult and expensive to achieve. Ingestion of lead paint by children with pica (the abnormal ingestion of non-food substances, a relatively common trait in pre-school children, particularly ages 1-3) is generally regarded as "the principal environmental source in cases of severe acute lead poisoning in young children." NAS Report at 140. Lead-based paint was widely used in pre-1940 housing, for both interiors and exteriors, so children living in older housing, particularly in urban ghettos where such paint is both present and peeling, are most susceptible to this form of lead poisoning. Limited control has been achieved in that lead paints are now rarely used, and

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[5] Lead in food and water ultimately can be traced to lead in soil and this, of course, is uncontrollable. The NAS Report concluded that "[t]here is no evidence that the amount of lead in the diets of people has changed substantially since 1940." NAS Report at 206.

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are frequently banned by statute, for interior surfaces. But while some local laws require removal of existing peeling lead paints, and there is federal legislation to aid states and municipalities in such efforts, Lead-Based Paint Poisoning Prevention Act, 42 U.S.C. §§ 4801 *et seq.*, (1970), there is no concentrated national effort at removal, and the danger to children living in dilapidated housing will remain for some time.[6]

The last remaining major source of lead exposure for humans is the ambient air. This source is easily the most controllable, since approximately 90 percent of lead in the air comes from automobile emissions,[7] and can be simply eliminated by removing lead from gasoline.[8] While the extent to which such lead actually enters the body is vigorously contested by petitioners and lies at the heart of this appeal, all parties agree that, to some extent at least, airborne lead can be absorbed through the lungs as a person breathes lead-contaminated air and that it can be eaten by children with pica after larger lead particles fall to the ground and mix with dust. Once the lead is in the body, however, its source becomes irrelevant; all lead in the bloodstream, from whatever source, is essentially fungible. Thus so long as there are multi-

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[6] A list of local laws regarding control and/or removal of lead-based paints can be found in NAS Report at 77.

[7] This is EPA's figure, Third Health Document at II-4, JA 37, and Ethyl Corporation (hereinafter Ethyl), alone among the petitioners, contests it. Supplemental brief of petitioner Ethyl Corporation (hereinafter Ethyl Supp. Br.) at 40. We cannot say that EPA's estimate is unreasonable. It was determined by discounting the NAS Panel's conclusion that "about 98% of the airborne lead that can be traced to its source comes from combustion of gasoline." NAS Report at 31. *See also id.* at 12-13.

[8] An alternative approach, considered and rejected by EPA, is to trap and remove lead emissions from the exhausts of automobiles using leaded gasoline. *See* note 66 *infra*.

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ple sources of lead exposure it is virtually impossible to isolate one source and determine its particular effect on the body. The effect of any one source is meaningful only in cumulative terms.

The multiple sources of human exposure to lead explain in part why it has been difficult to pinpoint automobile lead emissions as a danger to public health. Obviously, any danger is caused only by the additive effect of lead emissions on the other, largely uncontrollable, sources of lead. For years the lead antiknock industry has refused to accept the developing evidence that lead emissions contribute significantly to the total human lead body burden. In the Clean Air Act Amendments of 1970, Pub. L. 91-604, December 31, 1970, 84 STAT. 1698-1700, however, Congress finally set up a legal mechanism by which that evidence could be weighed in a more objective tribunal. It gave the newly-created EPA authority to control or prohibit the sale or manufacture of any fuel additive whose emission products "will endanger the public health or welfare * * *." 42 U.S.C. § 1857f-6c(c)(1)(A) (1970). It is beyond question that the fuel additive Congress had in mind was lead.[9]

Given this mandate, EPA published on January 31, 1971 advance notice of proposed rule-making. The Administrator announced he was considering possible controls on lead additives in gasolines, both because of their possible danger to health and because of their incompatibility with the newly-developed catalytic converter emission control system.[10] 36 FED. REG. 1486 (1971).

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[9] *See, e.g.*, 116 CONG. REC. 19207 (1970) (remarks of Rep. Skubitz) ("the Government can require that the oil companies get the lead out"); *id.* at 19228-19230 (colloquy between Reps. Waggoner & Staggers); *id.* at 19234 (remarks of Rep. Williams); *id.* at 19239 (remarks of Rep. Sebelius).

[10] Regulations promulgated for the latter reason were approved in *Amoco Oil Co.* v. *EPA*, *supra* note 2. *See* note 2 *supra*.

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Proposed regulations were issued a year later, February 23, 1972, supported by a document *Health Hazards of Lead*[11] (hereinafter First Health Document), prepared by the EPA scientific staff. Comments were invited for a 90-day period, later reopened for an additional 30 days. 37 FED. REG. 11786-11787 (1972). At the same time public hearings were held in Washington, D. C., Dallas, and Los Angeles.

On January 10, 1973 the Administrator, while issuing final regulations requiring availability of some lead-free gasoline to allow implementation of the catalytic converter system, 38 FED. REG. 1254; *approved in Amoco Oil Co.* v. *EPA*, 163 U.S.App.D.C. 162, 501 F.2d 722 (1974), reproposed the health-based regulations now at issue. 38 FED. REG. 1258. The reproposal was supported by a second health document, *EPA's Position on the Health Effects of Airborne Lead* (hereinafter Second Health Document), JA 158, and was necessitated by a modification of EPA's analysis of the health effects of lead emissions. The Agency concluded, after considering the comments received, that it was virtually impossible to identify the precise amount of airborne lead that will endanger public health. Instead, the control strategy would concentrate on evaluating the cumulative effect of airborne lead on total human lead exposure and the significance of that contribution. 38 FED. REG. 1258. The reproposed regulations themselves were similar to the original proposal, requiring a phased cutback to 1.25 grams of lead per gallon of leaded gasoline, but, in recognition of the industry's lead-time problems, pushing the timetable for reduction back one year. The Agency again invited public comment, this time for a 60-day period.

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[11] JA 292. This document was subsequently revised by HEALTH HAZARDS OF LEAD (rev. April 11, 1972), JA 254; ATMOSPHERIC LEAD AND PUBLIC HEALTH, (April 11, 1972), JA 276; and CORRECTIONS AND ADDITIONS TO HEALTH HAZARDS OF LEAD (April 27, 1972), JA 272.

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On October 28, 1973, as a result of a motion filed in *Natural Resources Defense Council, Inc.* v. *EPA*, D.C. Cir. No. 72-2233, this court ordered EPA to reach within 30 days a final decision on whether lead additives should be regulated for health reasons. EPA published its final health document, entitled *EPA's Position on the Health Implications of Airborne Lead*, on November 28, 1973. JA 27. This document, the Third Health Document, extensively details and reviews the state of knowledge of the health effects of airborne lead. It candidly discusses the various scientific studies, both pro and con, underlying this information, and ultimately concludes that lead from automobile emissions will endanger the public health. The same day, based largely on the conclusions of the Third Health Document, EPA promulgated its final regulations, accompanied by a thorough discussion of its health conclusions, the impact of the regulations, and the alternative courses of action considered and rejected. 38 FED. REG. 33734. The final regulations require the same step-wise reduction of lead additives but, in response to the comments of a majority of refiners, calculate the reduction in a slightly different manner. Whereas the original and reproposed regulations set standards for permissible lead use by each refiner on the basis of grams of lead per gallon of *leaded* gasoline produced (leaded pool averaging), the final regulations base the standards on grams of lead per gallon of all gasoline produced (total pool averaging). The quantity of lead emitted into the atmosphere is the same under both systems; EPA simply converted its leaded pool figures into total pool figures. Under the final regulations, lead in all gasoline would be reduced over a five-year period to an average of 0.5 grams per gallon.[12]

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[12] The reduction would proceed in the following steps:

1.7 g/gal. after Jan. 1, 1975
1.4 g/gal. after Jan. 1, 1976

[continued]

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Petitioners, various manufacturers of lead additives and refiners of gasoline, appealed the promulgation of low-lead regulations to this court under Section 307 of the Clean Air Act, 42 U.S.C. § 1857h-5. The appeal was heard by a division of the court on September 9, 1974. On December 20, 1974, the division, one judge dissenting, ordered the regulations set aside. The majority and dissenting opinions were published on January 28, 1975.[13] Because of the importance of the issues presented, we granted EPA's petition for rehearing *en banc* on March 17, 1975, vacating the judgment and opinions of the division and setting the case for reargument on May 30, 1975. All parties were invited to submit supplementary briefs addressing the issues raised by the division opinions.

The regulations are challenged by petitioners on a variety of grounds, all of which will be addressed below. Their primary claims, and the ones on which the division

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1.0 g/gal. after Jan. 1, 1977
0.8 g/gal. after Jan. 1, 1978
0.5 g/gal. after Jan. 1, 1979

40 C.F.R. § 80.20 (1975). According to EPA calculations, when the overall lead content of both leaded and unleaded gasoline averages 0.5 grams per gallon, leaded gasoline would contain an average of 1.25 grams of lead per gallon, the same as under the original regulations. *See* 38 FED. REG. at 33739 (1973).

[13] Commentators have been uniformly critical of the majority opinion. *See* Gardner, *Federal Courts and Agencies: An Audit of the Partnership Books*, 75 COLUM. L. REV. 800, 801 & n.77 (1975); Note, *Judicial Review of the Facts in Informal Rulemaking: A Proposed Standard*, 84 YALE L.J. 1750, 1767-68 & nn. 81-82 (1975); Note, *Reserve Mining—The Standard of Proof Required to Enjoin an Environmental Hazard to the Public Health*, 58 MINN. L. REV. 893, 918-19 n.116 (1975). *See also Reserve Mining Co.* v. *EPA*, 514 F.2d 492, 519-520 (8th Cir. 1975) (*en banc*).

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majority based its reversal, are that the Administrator misinterpreted the statutory standard of "will endanger" and that his application of that standard is without support in the evidence and arbitrary and capricious.

II. The Statutory Requirements

Under Section 211(c)(1)(A) the Administrator may, on the basis of all the information available to him, promulgate regulations that

> control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive for use in a motor vehicle or motor vehicle engine (A) if any emission products of such fuel or fuel additive will endanger the public health or welfare * * *.

42 U.S.C. § 1857-6c(a)(1)(A). The Administrator cannot act under Section 211(c)(1)(A), however, until after "consideration of all relevant medical and scientific evidence available to him, including consideration of other technologically or economically feasible means of achieving emission standards under [Section 202]." Section 211(c)(2)(A), 42 U.S.C. § 1857f-6c(c)(2)(A). Section 202 of the Act, 42 U.S.C. § 1857f-1, allows the Administrator to set standards for emission of pollutants from automobiles (as opposed to standards for the composition of the gasoline that produces the emissions), and is thus the preferred—although not the mandatory—alternative under the statutory scheme, presumably because it minimizes Agency interference with manufacturer prerogatives.[14]

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[14] When EPA acts under § 211(c)(1)(A) it is essentially telling manufacturers how to make their fuels, a task Congress felt the Agency should enter upon only with trepidation. *See, e.g.*, 116 Cong. Rec. 32920 (1970) (remarks of Sen. Baker); *id.* at 19229 (remarks of Reps. Rogers & Waggoner).

[continued]

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The Administrator is also required, before prohibiting a fuel or fuel additive under Section 211(c)(1)(A), to find, and publish the finding, that in his judgment any fuel or fuel additive likely to replace the prohibited one will not "endanger the public health or welfare to the same or greater degree * * *." Section 211(c)(2)(C), 42 U.S.C. § 1857f-6c(c)(2)(C). It is significant that this is the *only* conclusion the Administrator is expressly required to "find" before regulating a fuel or fuel additive for health reasons.

A. *The Threshold Determination*

In making his threshold determination that lead particulate emissions from motor vehicles "will endanger the public health or welfare," the Administrator provided his interpretation of the statutory language by couching his conclusion in these words: such emissions "present a significant risk of harm to the health of urban populations, particularly to the health of city children." 38 FED. REG. 33734. By way of further interpretation, he added that it was his view

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On the other hand, when the Agency acts under § 202, it is only mandating an end product—regulated emissions. The method for achieving the required result is entirely in the hands of the manufacturers.

Nonetheless, deference to regulation under § 202 is not mandatory. The Administrator is only required to "consider" the possibility of regulating under that section instead of under § 211. This language is in sharp contrast to the version of § 211 that was passed by the House. The House version would have allowed regulation under § 211 only after the Administrator made a specific finding "that it is not otherwise technologically or economically feasible to achieve the emission standards established pursuant to section 202 of this Act." H.R. 17255, 91st Cong., 2d Sess. § 210(g)(1) (1970). This mandatory deference to § 202 regulation was removed in conference and the present more flexible language was substituted. *See* pages 40-43 *infra*.

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> that the statutory language * * * does not require a determination that automobile emissions alone create the endangerment on which controls may be based. Rather, the Administrator believes that in providing this authority, the Congress was aware that the public's exposure to harmful substances results from a number of sources which may have varying degrees of susceptibility to control.

Id. It is petitioners' first claim of error that the Administrator has erroneously interpreted Section 211(c)(1)(A) by not sufficiently appreciating the rigor demanded by Congress in establishing the "will endanger" standard. Therefore, petitioners argue, the Administrator's action is "short of statutory right," in violation of Section 10(e)(2)(C) of the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(C) (1970).

Petitioners argue that the "will endanger" standard requires a high quantum of factual proof, proof of actual harm rather than of a "significant risk of harm." *See* Supplemental brief of petitioner Ethyl Corporation (hereinafter Ethyl Supp. Br.) at 20. Since, according to petitioners, regulation under Section 211(c)(1)(A) must be premised upon factual proof of actual harm, the Administrator has, in their view, no power to assess risks or make policy judgments in deciding to regulate lead additives. Moreover, petitioners argue, regulation must be based on the danger presented by lead additives "in and of themselves," so it is improper to consider, as the Administrator did, the cumulative impact of lead additives on all other sources of human exposure to lead. We have considered these arguments with care and find them to be without merit.[15] It is our view that the

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[15] At oral argument, petitioners claimed the regulations were void because the Administrator had failed to couch his ultimate finding in the language of the statute itself. *See also* Supplemental brief of petitioner National Petroleum Refiners

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Administrator's interpretation of the standard is the correct one.[16]

1. *The Precautionary Nature of "Will Endanger."* Simply as a matter of plain meaning, we have difficulty crediting petitioners' reading of the "will endanger"

Association (hereinafter NPRA Supp. Br.) at 5. The short answer to the argument is that petitioners' view of the facts is erroneous. While interpreting the "will endanger" standard to mean "presents a significant risk of harm," 33 FED. REG. 33734, the Administrator ultimately did make his finding in the language of the statute:

> These regulations are based upon a determination by the Administrator that the emission product of a fuel or additive will endanger the public health * * *.

Id. at 33741. *See* 40 C.F.R. § 80.1 (1974).

In any case, however, the issue is spurious. It is well established that ultimate findings do not have to be expressed at all, let alone be expressed in the language of the statute. Rather, absent compelling countervailing considerations, an ultimate finding will be implied from the action taken. *Pacific States Box & Basket Co.* v. *White*, 296 U.S. 176, 186 (1935); *Martin* v. *Mott*, 25 U.S. (12 Wheat.) 19, 32-33 (1827) (Story, J.). *Cf. Joseph* v. *FCC*, 131 U.S.App.D.C. 207, 211-212, 404 F.2d 207, 211-212 (1968). The law is fully developed in 2 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 16.07 at 455-59 (1958).

[16] We note that even if we did not agree fully with the Administrator's interpretation of the Act, we would be obliged to accord it considerable deference. As the Supreme Court recently held in approving, despite the contrary views of several circuits, the Administrator's reading of another section of the Clean Air Act:

> Without going so far as to hold that the Agency's construction of the Act was the only one it permissibly could have adopted, we conclude that it was at the very least sufficiently reasonable that it should have been accepted by the reviewing courts.

Train v. *Natural Resources Defense Council, Inc.*, 421 U.S. 60, 75 (1975). *See also id.* at 87.

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standard. The meaning of "endanger" is not disputed. Case law and dictionary definition agree that endanger means something less than actual harm.[17] When one is endangered, harm is *threatened;* no actual injury need ever occur. Thus, for example, a town may be "endangered" by a threatening plague or hurricane and yet emerge from the danger completely unscathed.[18] A stat-

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[17] It is linguistically clear, of course, that one can be "endangered" without actually being harmed. Nonetheless, some risk of harm is necessary. *State* v. *Fine,* 324 Mo. 194, 23 S.W.2d 7, 9 (1929). Webster defines "endanger" as "to bring into danger or peril of *probable* harm or loss." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 748 (1961) (emphasis added).

Not all courts have agreed that "probability" of harm is the proper determinant of danger. Where grounds for divorce are few, for instance, courts have interpreted laws allowing divorce because of inhuman treatment that "endangers the life" to require only the slightest possibility of actual loss of life. Thus action that endangers health has been held to endanger life on the theory that the former cannot be endangered without threatening the latter. *See Cole* v. *Cole,* 23 Iowa 433, 438 (1867); *Beebe* v. *Beebe,* 10 Iowa 133, 139 (1859). In one of the latest of these cases, mistreatment that deprived a spouse of needed rest and peace of mind was held to "endanger" life. *Smith* v. *Smith,* 258 Iowa 557, , 138 N.W.2d 453, 456 (1966). We need not decide here how remote the possibility of actual harm could be under the "will endanger" standard since we accept the Administrator's determination in this case that a "significant" risk to health falls within the statutory language. *See* pages 31-36 *infra.*

[18] Petitioner Ethyl suggests that while these may indeed be examples of endangerment they differ from the threat from automotive lead emissions in that

> plagues do cause death and illness; violent storms do cause damage—known facts that may be experienced by the threatened community.

Ethyl Supp. Br. at 11 (footnote omitted). We may preliminarily observe that the absorption of lead does cause lead poisoning, a known fact that may be evaluated by the public

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ute allowing for regulation in the face of danger is, necessarily, a precautionary statute. Regulatory action may be taken before the threatened harm occurs; indeed, the very existence of such precautionary legislation would seem to *demand* that regulatory action precede, and, optimally, prevent, the perceived threat. As should be apparent, the "will endanger" language of Section 211 (c) (1) (A) makes it such a precautionary statute.

The Administrator read it as such, interpreting "will endanger" to mean "presents a significant risk of harm." 38 FED. REG. 33734. We agree with the Administrator's interpretation. This conclusion is reached not only by reference to the plain meaning of the statute, but by juxtaposition of Section 211 (c) (1) (A) with other sections of the Clean Air Act and by analysis of pertinent precedent.[19]

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and the EPA. However, in so far as Ethyl is complaining that the mechanism by which plagues and storms cause damage is well known while the question of the relation between lead automobile emissions and the absorption of lead is less certain, Ethyl's observation only supports the reading of § 211 (c) (1) (A) as a precautionary statute. The massive diffusion of airborne lead is a gross environmental modification never before experienced. Of course, there are no past disasters of the kind anticipated by the Administrator on which the community's experience may be based. This, however, is inherent in such a threat and does not imply that no danger is posed by it. We believe the precautionary language of the Act indicates quite plainly Congress' intent that regulation should precede any threatened, albeit unprecedented, disaster. Ethyl is correct that we have not had the opportunity to learn from the consequences of an environmental overdose of lead emissions; Congress, however, sought to spare us that communal experience by enacting § 211 (c) (1) (A).

[19] Since Congress seemed to assume that the meaning of the threshold determination required by § 211 (c) (1) (A) would be self-evident, there is a complete absence of

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Petitioners support their view of the rigorous nature of the "will endanger" standard by relying on two other sections of the Clean Air Act that also allow for regulation of air pollutants for health reasons. Ethyl Supp. Br. at 18-23; supplemental brief of petitioner Nalco Chemical Company (hereinafter Nalco Supp. Br.) at 20-25; NPRA Supp. Br. at 31-46. However, we find in the same sections relied upon by petitioners firm support for our view of the precautionary nature of Section 211(c)(1)(A). The provisions identified by petitioners are Sections 108 and 202 of the Act. Section 108 directs the Administrator to list, for the purpose of establishing national primary and secondary ambient air quality standards pursuant to Section 109, each air pollutant "which in his judgment has an adverse effect on public health or welfare * * *." Section 108(c)(1)(A), 42 U.S.C. § 1857 c-3(a)(1)(A). Section 202 authorizes the Administrator to set standards for each automobile emission "which in his judgment causes or contributes to, or is likely to cause or contribute to, air pollution which endangers the public health or welfare." Section 202(a)(1), 42 U.S.C. § 1857f-1(a)(1).

Petitioners suggest that the threshold decision to regulate under both Section 108 and Section 202 can be based on less evidence than required under Section 211 and that, therefore, the proof necessary for action under Section 211 must be particularly firm. Petitioners misread both sections. Section 108 requires an actual "adverse effect" on health before an air pollutant may be listed for regulation; actual harm must result.[20] This

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helpful legislative history. What little there is of relevance is discussed at pages 38-43 *infra*. *See also* note 89 *infra*.

[20] Should there be any doubt about this conclusion, it is quickly resolved by reference to § 109. There Congress

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firm threshold finding is reasonable in light of the considerable disruption caused by action under Sections 108-110. After a pollutant is listed under Section 108, the Administrator must issue national ambient air quality standards under Section 109 within a year. Promulgation of standards begins the implementation plan process of Section 110 under which the states must control, on a mandatory timetable, the listed pollutants to the extent necessary to achieve the federal standards. Section 110, 42 U.S.C. § 1857c-5. Sections 108-110 are "technology forcing" provisions; the attainment of the primary, health-based standards takes precedence over the cost and present technological feasibility of achieving the requisite control. *Union Electric Co.* v. *EPA*, 515 F.2d 206, 215-16 (8th Cir.), *cert. granted*, —— U.S. ——, 44 U.S. L. WEEK 3200 (Oct. 6, 1975). *Cf. Train* v. *Natural Resources Defense Council*, 421 U.S. 60, 90-91 (1975). *See also* S. Rep. No. 91-1196, 91st Cong., 2d Sess. 1-3 (1970).

Thus, before ordering this extensive chain of action to begin, Congress demanded a threshold determination that the pollutant causes actual harm.[21] In this sense

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made it quite clear how it would refer to anything other than actual harm. Section 109(b)(2) provides that national secondary ambient air quality standards for pollutants listed under § 108 be prescribed with a margin of safety; they should be sufficient to protect against "any *known or anticipated* adverse effects associated with the presence of such air pollutant in the ambient air." 42 U.S.C. § 1857c-4(b)(2) (emphasis added). When Congress uses the phrase in § 108 without the modifier "known or anticipated" it plainly embraces only the usual meaning of adverse effects, *i.e.*, known adverse effects or actual harm.

[21] The Administrator appears to have a measure of discretion in determining whether to list a pollutant under § 108, which, by its terms, speaks of the exercise of his "judgment." *See* 38 FED. REG. 33740 (1973). *Amicus* Natural Resources Defense Council (NRDC) has argued that listing of

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Section 108 is not a precautionary statute at all, and so differs sharply from Section 211. However, the effects of such after-the-fact regulation are somewhat ameliorated by the Act; Congress did provide a precautionary element in standard-setting under Sections 108-110. Section 109 expressly requires that the ambient air standards ultimately issued provide for "an adequate margin of safety." 42 U.S.C. § 1857c-4(b)(1). Thus, while the threshold decision to regulate under Sections 108-110 is not precautionary but rather requires proof of demonstrable harm caused by the suspect pollutant, once the decision is made the standards promulgated must be preventive in nature. Congress' choice of this scheme is in direct contrast to the procedures it established under Section 211. Under that section the decision to regulate is based on perceived danger. Unless we are to assume Congress chose its language carelessly, regulation in the face of "danger" rather than in the face of "adverse effects" must mean that the threshold decision to regulate under Section 211 is precautionary.[22] The contrast between the standards of Sections 108-110 and of Section 211 supports our view of the precautionary nature of the "will endanger" standard.[23]

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air pollutants under § 108 is mandatory. Its petition for review of these regulations raising that issue was dismissed by the division for want of jurisdiction, *Natural Resources Defense Council, Inc.* v. *EPA*, No. 74-1023 (D.C. Cir. September 11, 1974), and NRDC has since brought a successful citizen's suit under § 304 of the Act, 42 U.S.C. § 1857h-2, to compel issuance of national ambient air standards for lead. *Natural Resources Defense Council, Inc.* v. *Train*, No. 74-Civ-4617 (S.D.N.Y. decided March 1, 1976).

[22] Thus we must reject *amicus* NRDC's suggestion that the standards for action under §§ 108 and 211 are the same.

[23] Petitioners' arguments that the threshold determination under the "adverse effect" standard is less rigorous than under the "will endanger" standard are either spurious or mis-

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Petitioners also rely on Section 202 to support their strict reading of Section 211. Ethyl suggests that Section 202 is more lenient than Section 211 in that it allows regulation of "likely" dangers. Ethyl Supp. Br. at 18-19. *See also* Nalco Supp. Br. at 20-21; NPRA Supp. Br.

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directed. Nalco Chemical Company (Nalco) and Ethyl argue that the presence of the phrase "in his judgment" in § 108, and its absence in § 211, means the Administrator has greater discretionary power under the former section. Ethyl Supp. Br. at 21; Nalco Supp. Br. at 22. As we shall explain below, *see* note 37 *infra*, the Administrator retains the same (if not greater, *see* note 21 *supra*) discretionary power under § 211.

Nalco points to the "margin of safety" language of § 109 as proof of a "lower standard" under § 108, Nalco Supp. Br. at 22, without recognizing that the margin of safety refers only to the implementing requirement of formulating standards and not to the threshold decision to regulate. NPRA likewise confuses this point by suggesting that the listing requirement of § 108 is like the reporting requirements of § 211(a), so that the "margin of safety" language is comparable to § 211(c)(1)(A), only more generous. NPRA Supp. Br. at 42-43. This ignores the fact that once a pollutant is listed under § 108 the decision to regulate is made; standards under § 109 must follow. On the other hand, additives reported under § 211(a) are not necessarily regulated; regulations are premised only on a § 211(c)(1)(A) finding of endangerment. Thus, as suggested in the text, the threshold determination under § 108 is properly compared to the threshold determination under § 211(c)(1)(A).

Ethyl argues that an "adverse effect" does not have as severe a connotation as "endangerment." Ethyl Supp. Br. at 19 n.27. Even if true, however, this argument has nothing to do with whether the threshold determination to regulate is, or is not, precautionary. Even if § 108 allowed regulation of less severe effects than does § 211, regulations could still be premised only on a finding of an *actual* effect, while § 211 regulations could still be premised on a precautionary finding of *threatened*, albeit more severe, harm.

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at 31-36. Section 202 provides that the Administrator may regulate

> the emission of any air pollutant [from any new motor vehicle] which in his judgment *causes or contributes to, or is likely to cause or contribute to,* air pollution which endangers the public health or welfare.

42 U.S.C. § 1857f-1(a)(1) (emphasis added). While this language may be unnecessarily opaque, we think a fair reading disproves petitioners' suggestion. The italicized language upon which petitioners rely refers not to the causal relationship between air pollution and health, but to the relationship between automobile emissions and air pollution.[24] Thus regulation may not be premised on a threshold determination of likely danger; rather regulation must be premised on a determination of danger, a finding that "*air pollution which endangers the public health*" is the end product of the emission to be regulated. This is essentially the same finding of endangerment as under Section 211. "Likely" enters the equation only in determining whether the emitted air pollutant, which would be regulated, contributes to the air pollution which is found dangerous. Here the statute allows for a somewhat attenuated chain of causation. Regulation may be premised on a determination that an air pollutant emitted from a new automobile is likely to contribute to air pollution which endangers the public health. In establishing this chain of causation

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[24] In essence, petitioners are suggesting § 202 is more properly read to provide for regulation of any automotive emission

> which in his judgment causes or contributes to, or is likely to cause or contribute to, *air pollution which causes or contributes to, or is likely to cause or contribute to,* the endangerment of the public health or welfare.

Quite obviously, this is not what Congress said.

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Section 202 is more lenient than Section 211,[25] but in making the threshold determination of danger both sections are the same:[26] air pollution must endanger the public health before regulation is justified.[27]

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[25] Section 211 simply skips this chain of causation and requires instead that the emission products of the fuel additive to be regulated endanger the public health. This omission of a step does not support petitioners' "in and of itself" theory, *see* pages 56-61 *infra*, but rather is responsive to the different intendments of §§ 101 and 211. *See* note 27 *infra*. In any case, it is plain that for regulation under § 211 the emission products must directly (although not necessarily by themselves) endanger the public health; whether they contribute to air pollution that in turn endangers the public health, as required by § 202, is irrelevant. Since the Administrator found that lead emissions directly endanger the public health, whatever leniency § 202 provides is irrelevant to this case.

Nalco takes issue with the dismissal of this question and asks sarcastically, "If causation is irrelevant to the regulation of fuel additives, why is EPA concerned about meeting any standard at all in these regulations." Nalco Supp. Br. at 20-21. Nalco is confusing two separate causation issues. There is undoubtedly a causation issue about whether lead emissions cause a danger to public health. On the other hand, however, there is no causation issue about whether lead emissions contribute to lead air pollution. There is no such issue, first, because § 211, unlike § 202, does not demand such a finding and, second, because in any case petitioners could not, and do not, contest the validity of that assertion. It is only this issue of causation, to which the "likely" language of § 202 relates, that EPA argues, and we agree, is irrelevant to this case. *See* EPA Supp. Br. at 17-18.

[26] Thus while Congress preferred emission regulation under § 202 to fuel content regulation under § 211, *see* note 14 *supra*, there is no reason to assume, as NPRA argues, NPRA Supp. Br. at 31-35, that in situations where § 211 regulation is proper, the Administrator must find greater potential harm before acting. *Cf.* note 23 *supra*.

[27] NPRA recognizes that a literal reading of § 202 produces the result suggested above. Thus it argues that this

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Thus the two sections of the Clean Air Act presented by petitioners in support of their stringent reading of the threshold requirement for action under Section 211 turn out, upon analysis, to be of no support at all. Section 108 only bolsters our reading of Section 211 as a precautionary statute while Section 202 includes the same standard as Section 211 and thus is of no guidance one way or the other. While petitioners have little more to offer to prove that the "will endanger" standard demands proof of actual harm and is not precautionary in nature, we may turn, in support of our interpretation, to the relevant case law. While cases interpreting the

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result is "meaningless, or at best tautological," NPRA Supp. Br. at 32, so that its "likely" danger theory emerges as an acceptable, although linguistically incorrect, alternative. *Id.* at 33. NPRA argues that the above reading would require

> the Administrator to determine whether "the emission of any *air pollutant* . . . is likely to cause or to contribute to, *air pollution* . . . ."

Id. at 32 (emphasis in original). Since under this reading, NPRA argues, the Administrator would always reach a positive conclusion, this reading must be incorrect. We agree that this reading is of little value, but we do not think it is the proper result of our analysis above. Rather, we think that to regulate under § 202 the Administrator must find that emission of the air pollutant is likely to cause or contribute to *dangerous* air pollution. This addition is important, for not all air pollutants contribute to dangerous air pollution and, more importantly, not all dangerous air pollution is caused by air pollutants that are, themselves, dangerous. Thus hydrocarbons, whose emission is regulated by § 202, are not themselves always dangerous, but are properly regulated because they react in sunlight to form smog, which is dangerous. *See* S. Rep. 89-192, 89th Cong., 1st Sess. 5-6 (1965); EPA Supp. Br. at 18 n.15. Thus, far from stating a tautology, § 202 allows for the regulation of such apparently innocent pollutants, which indirectly cause dangerous pollution.

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meaning of "endanger" are few in number,[28] at least one recent case is directly on point and fully in accord with our view.

In *Reserve Mining Co.* v. *EPA*, 514 F.2d 492 (8th Cir. 1975) (*en banc*), the Eighth Circuit addressed, among other issues, the meaning of the phrase "endangering the health or welfare of persons" under Section 1160 of the Federal Water Pollution Control Act of 1970 (FWPCA), 33 U.S.C. § 1160. FWPCA and the Clean Air Act together constitute the bulk of this nation's substantive environmental protection legislation.[29] As

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[28] *See* note 17 *supra*. *See also Environmental Defense Fund, Inc.* v. *EPA*, 150 U.S.App.D.C. 348, 465 F.2d 528 (1972), where in interpreting the more rigorous statutory language "imminent hazard" which must be found before the registration for a pesticide may be suspended pending the conclusion of cancellation proceedings, 7 U.S.C. § 136d(c) (Supp. II 1972), we concluded, per Judge Leventhal:

> It is enough if there is *substantial likelihood* that serious harm will be experienced during the year or two required in any realistic projection of the administrative process.

Id. at 360, 465 F.2d at 540 (emphasis added).

In another case interpreting the standards for cancellation of a pesticide under the same statute, we held, per Judge Wilkey, that a showing of "potentially great dangers from DDT" sufficed as a basis for cancellation. *Environmental Defense Fund, Inc.* v. *EPA* (Coahoma), 160 U.S.App.D.C. 123, 128, 489 F.2d 1247, 1252 (1973).

[29] *Cf.* Environmental Education Act, 20 U.S.C. § 1531 *et seq.*; Environmental Quality Improvement Act of 1970, 42 U.S.C. § 4371 *et seq.*; National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. § 4321 *et seq.* While initially the procedural requirements of NEPA consumed judicial energies most conspiciously, *see, e.g., Natural Resources Defense Council* v. *Morton*, 148 U.S.App.D.C. 5, 458 F.2d 827 (1972); *Calvert Cliffs' Coordinating Committee, Inc.* v. *AEC*, 146 U.S.App.D.C. 33, 449 F.2d 1109 (1971), courts are increas-

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such, and because of their contemporaneous enactment, interpretations of provisions of one Act have frequently been applied to comparable provisions of the other. *See, e.g., Natural Resources Defense Council, Inc.* v. *Train*, 166 U.S.App.D.C. 312, 321-322, 510 F.2d 692, 701-702 (1975). Thus *Reserve Mining's* interpretation of "endangering" is relevant to the meaning of the term "endanger" in the Clean Air Act. Indeed, it is particularly relevant because in construing the language before it the Eighth Circuit borrowed extensively from the interpretation of the "will endanger" language of Section 211 expressed in the dissent from the division opinion in this case, the same interpretation we adopt here. *See Reserve Mining Co.* v. *EPA, supra*, 514 F.2d at 528-529. After analysis of the plain meaning of the FWPCA provision, comparison with other sections of that Act, and reference to our division's dissent, the Eighth Circuit's unanimous conclusion fully supports our view of the "will endanger" standard:

> In the context of this environmental legislation, we believe that Congress used the term "endangering" in a precautionary or preventive sense, and, therefore, evidence of potential harm as well as actual harm comes within the purview of that term.

Id. at 528.

In sum, based on the plain meaning of the statute, the juxtaposition of Section 211 with Sections 108 and 202, and the *Reserve Mining* precedent, we conclude that the "will endanger" standard is precautionary in nature and

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ingly according substantive weight to the NEPA language. *See Sierra Club* v. *Morton*, —— U.S.App.D.C. ——, ——-—— & n.25, 514 F.2d 856, 873-875 & n.25 (1975), and cases cited therein, *cert. granted, sub nom. Kleppe* v. *Sierra Club*, —— U.S. ——, 44 U.S. L. WEEK 3397 (Jan. 12, 1976).

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does not require proof of actual harm before regulation is appropriate.[30]

Perhaps because it realized that the above interpretation was the only possible reading of the statutory language, petitioner Ethyl addresses this interpretation and argues that even if actual harm is not required for action under Section 211(c)(1)(A), the occurrence of the threatened harm must be "probable" before regulation is justified. Ethyl Supp. Br. 12. While the dictionary admittedly settles on "probable" as its measure of danger,[31] we believe a more sophisticated case-by-case analysis is appropriate. *See* note 17 *supra*. Danger, the Administrator recognized, is set not by a fixed probability of harm, but rather is composed of reciprocal elements of risk and harm, or probability and severity. *Cf. Carolina Environmental Study Group* v. *United States*, 166 U.S.App.D.C. 416, 419, 510 F.2d 796, 799 (1975); *Reserve Mining Co.* v. *EPA*, *supra*, 514 F.2d at 519-520. That is to say, the public health may properly be found endangered both by a lesser risk of a greater harm and by a greater risk of a lesser harm.[32] Danger depends

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[30] *See* Green, *The Risk-Benefit Calculus in Safety Determinations*, 43 GEO. WASH. L. REV. 791 (1975); Handler, *A Rebuttal: The Need for a Sufficient Scientific Base for Government Regulation*, *id.* at 808. Both authors agree that government safety determinations should be preventive and based on assessment of risks. Dr. Handler differs from Professor Green in arguing that risks should be quantified before regulatory decisions are made. Professor Green believes that quantification is not always necessary or possible, and that the public health is better served by the making of value judgments, however inexact.

[31] *See* note 17 *supra*.

[32] This proposition must be confined to reasonable limits, however. In *Carolina Environmental Study Group* v. *United States*, 166 U.S.App.D.C. 416, 510 F.2d 796 (1975), a division of this court found the possibility of a Class 9 nuclear reactor

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upon the relation between the risk and harm presented by each case, and cannot legitimately be pegged to "probable" harm, regardless of whether that harm be great or small. As the Eighth Circuit found in *Reserve Mining*, these concepts "necessarily must apply in a determination of whether any relief should be given in cases of this kind in which proof with certainty is impossible." [33] 514 F.2d at 520.

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disaster, a disaster of ultimate severity and horrible consequences, to be so low that the Atomic Energy Commission's minimal consideration of the effects of such a disaster in an environmental impact statement prepared for a new reactor was sufficient. Likewise, even the absolute certainty of *de minimis* harm might not justify government action. Under § 211 the threatened harm must be sufficiently significant to justify health-based regulation of national impact. Ultimately, of course, whether a particular combination of slight risk and great harm, or great risk and slight harm, constitutes a danger must depend on the facts of each case.

[33] Nalco devotes several pages of its brief to arguing that there is a distinction between "risk" and "danger" that EPA fails to recognize. Nalco Supp. Br. at 9-11, *citing Reserve Mining Co.* v. *EPA*, *supra* note 13, and *Power Reactor Development Co.* v. *International Union of Electricians*, 367 U.S. 396 (1961). To the extent Nalco argues that risk and danger are not synonymous, Nalco battles with a straw man. EPA recognizes that a risk to public health is not necessarily a danger to public health; it only argues that a *significant* risk of widespread lead poisoning constitutes such a danger. To the extent Nalco argues there is no element of risk in danger, it is plainly wrong, as the cases it cites demonstrate. In support of its position, Nalco quotes the following language from *Reserve Mining*, in which the *en banc* court compares its present opinion with the "stay" opinion of a division of the court, *Reserve Mining Co.* v. *United States*, 498 F.2d 1073 (8th Cir. 1974), in which the division stayed the District Court's injunction ordering the immediate closing of the Reserve Mining plant:

> As will be evident from the discussion that follows, we adhere to our preliminary assessment that the evidence

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In *Reserve Mining* the issue was whether asbestiform wastes flushed into Lake Superior by the Reserve Mining Company endangered health.[34] The polluted lake

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is insufficient to support the kind of *demonstrable* danger to the public health that would justify the *immediate* closing of Reserve's operations. We now address the basic question of whether the discharges pose any risk to the public health, and, if so, whether the risk is one that is legally cognizable.

514 F.2d at 507. The Eighth Circuit is not drawing a sharp line between "danger" and "risk," but is only contrasting degrees of danger. Nalco fails to note that the "legally cognizable" *risk* ultimately found was that Reserve's discharges were "*endangering*" the public health within the meaning of the Federal Water Pollution Control Act. *See* page 34 *infra*. Necessarily, "risk" is an element of "danger," and the *Reserve Mining* court explicitly recognized that fact. 514 F.2d at 520.

The *Power Reactor* case is likewise of no support to Nalco. There the Supreme Court simply recognized that when regulations juxtaposed, and ordered, findings of "undue risk" and "endanger," an "undue risk" was not intended to mean "endanger." The Court did not say that risk was not an element of danger, only that in the regulations before it an "undue" risk was not necessarily a sufficient risk to constitute a "danger."

[34] *Reserve Mining* involved issues not only under FWPCA, but under § 407 of the Rivers and Harbors Act of 1899, 33 U.S.C. § 401 *et seq.*, the federal common law of public nuisance, and various Minnesota air and water pollution laws, Minn. Stat. Ann. § 116.081(1); *id.* § 115.07(1); *id.* § 105.41. Finding the evidence of danger posed by Reserve Mining's waste emissions into the air more compelling than that of the danger posed by the water emissions (since a correlation between *inhalation*, but not *ingestion*, of asbestos fibers and cancer could be found), the Eighth Circuit found the continued air emissions to be in violation of various Minnesota regulations and ordered Reserve to "promptly take all steps necessary to comply" with the law. *Reserve Mining Co.* v. *EPA*, *supra* note 13, 514 F.2d at 538. With respect to the

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waters formed the drinking supply of several surrounding communities, while a medical theory, bolstered only by inconclusive evidence, suggested that ingestion of the wastes caused cancer. *See* pages 93-94 *infra*. Applying the "endangering the health or welfare of persons" standard of the FWPCA, the court found the wastes to be a danger cognizable under the Act. The court did not find that the danger was probable; rather it found the wastes to be "potentially harmful," 514 F.2d at 528, and potential harm to be embraced by the "endangering" standard, *id.* *See* page 30 *supra*. The court concluded:

> The record shows that Reserve is discharging a substance into Lake Superior waters which under *an acceptable but unproved medical theory* may be considered as carcinogenic. As previously discussed, this discharge gives rise to a *reasonable medical concern* over the public health. We sustain the district court's determination that Reserve's discharge into Lake Superior constitutes pollution of waters "endangering the health or welfare of persons" within the terms of §§ 1160(c)(5) and (g)(1) of the Federal Water Pollution Control Act and is subject to abatement.

514 F.2d at 529 (footnote omitted) (emphasis added). The court thus allowed regulation of the effluent on only a "reasonable" or "potential" showing of danger, hardly the "probable" findirg urged by Ethyl as the proper reading of the "endanger" language in Section 211.

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water pollution, as described in the text, the court found the probabilities of danger to be

> low for they do not rest on a history of past health harm attributable to ingestion but on a *medical theory* implicating the ingestion of asbestos fibers as a causative factor in increasing the rates of gastrointestinal cancer among asbestos workers.

Id. at 536 (emphasis added). Thus the court only ordered cessation of dumping within a "reasonable time." *Id.* at 538.

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The reason this relatively slight showing of probability of risk justified regulation is clear: the harm to be avoided, cancer, was particularly great. However, because the risk was somewhat remote, the court did not order the immediate cessation of asbestiform dumping, but rather ordered such cessation within "a reasonable time." *Id.* at 538.

Reserve Mining convincingly demonstrates that the magnitude of risk sufficient to justify regulation is inversely proportional to the harm to be avoided. *Cf. Carolina Environmental Study Group* v. *United States*, *supra*. It would be a bizarre exercise in balancing horrors to determine whether cancer or lead poisoning is a greater harm to be avoided,[35] but fortunately such balancing is unnecessary in this case. Undoubtedly, the harm caused by lead poisoning is severe; nonetheless, the Administrator does not rely on a "potential" risk or a "reasonable medical concern" to justify the regula-

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[35] Petitioners properly point out that, unlike lead, there is no known safe human exposure level for carcinogens. Nalco Supp. Br. at 9; Ethyl Supp. Br. at 29. *See The Society of the Plastic Industry, Inc.* v. *OSHA*, 509 F.2d 1301, 1307 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975); *Industrial Union Department, AFL-CIO* v. *Hodgson*, 162 U.S.App.D.C. 331, 499 F.2d 467 (1974). This does not, however, imply that the harm caused by lead poisoning is less significant than that caused by cancer, only that safe human exposure levels to the causes of the two diseases may differ. This the Administrator recognized. Unlike the actions of the Secretary of Labor in the above cited cases, he did not order the lead content of gasoline reduced to the lowest detectable levels, but rather directed a phased cutback to what he deemed a safe level.

In any case, however, even if cancer is considered more serious than lead poisoning, the Administrator acted based on an assessment that the risk of lead poisoning from automobile emissions was considerably greater than the cancer risk that motivated the *Reserve Mining* court. Thus this greater risk of an arguably lesser harm still constitutes endangerment.

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tions before us. Instead, he finds a "significant" risk of harm to health. While this finding may be less than the "probable" standard urged by Ethyl, it is considerably more certain than the risk that justified regulation in *Reserve Mining* of a comparably "fright-laden" harm. *Cf. Environmental Defense Fund, Inc.* v. *EPA*, 150 U.S.App.D.C. 348, 358, 465 F.2d 528, 538 (1972). Moreover, like the *Reserve Mining* court, in the face of this still less than certain risk the Administrator did not order the cessation of use of lead additives, but rather directed a phased step-down to a plateau level. Thus we conclude that however far the parameters of risk and harm inherent in the "will endanger" standard might reach in an appropriate case, they certainly present a "danger" that can be regulated when the harm to be avoided is widespread lead poisoning and the risk of that occurrence is "significant." [36]

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[36] This conclusion that a "significant risk of harm" states a sufficient probability of occurrence to fall within the "will endanger" standard is bolstered by the fact that Congress did not employ various modifiers frequently used (in the Clean Air Act and elsewhere) to mandate more certain endangerment. Thus Congress did not require that the lead emissions "*clearly* endanger" the public health, *cf.* 21 U.S.C. § 454(c); *id.* § 661(c); 50 U.S.C. § 1517, or that the emissions pose an "*imminent and substantial* endangerment" to the public health, *cf.* 33 U.S.C. § 1364 (Supp. 1974); 42 U.S.C. § 300i(a); *id.* § 1851c-10(b); *id.* § 1857c-7(c)(1). *See Reserve Mining Co.* v. *EPA*, *supra* note 13, 514 F.2d at 528. We find these omissions more significant than the use of the modifier "will," which Ethyl argues adds "a particular degree of certainty to the probability that must be shown." Ethyl Supp. Br. at 12. To the contrary, "will" only makes it clear that the standard is one of danger and nothing less, a conclusion with which we agree.

Whether the evidence relied upon by the Administrator is sufficient to support his finding of a "significant risk of harm" is discussed below at pp. 66-97 *infra*.

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2. *The Administrator's Power to Assess Risks.* Petitioners argue that Section 211 requires the Administrator to make a "threshold factual determination" that automobile emissions "will endanger" the public health, Nalco Supp. Br. at 15-20; Ethyl Supp. Br. at 24-26, and dispute EPA's claim that the Administrator may make "an essentially legislative policy judgment, rather than a factual determination, concerning the relative risks of underprotection as compared to overprotection." *Industrial Union Department, AFL-CIO* v. *Hodgson*, 162 U.S.App.D.C. 331, 339, 499 F.2d 467, 475 (1974). We must reject petitioners' argument, since the power to assess risks, without relying solely on facts, flows inexorably from the nature of the "will danger" standard. We have already found that Section 211 allows the Administrator to regulate fuel content when he finds that emissions cause a significant risk of harm to the public health. Yet, how can the Administrator determine that a risk is a significant risk if he cannot assess risks? And how can he assess risks if he cannot make policy judgments? Surely reliance on "facts" as contemplated by petitioners will provide little guidance. However, sole reliance on facts was not demanded by Congress.[37]

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[37] Besides the arguments discussed below, petitioners support their claim that a "factual" not judgmental decision is required by pointing to the absence in § 211 of a phrase expressly allowing the Administrator to use his "judgment," in contrast to the presence of such a phrase in §§ 108 and 202. Nalco Supp. Br. at 21-22; Ethyl Supp. Br. at 21-22. The argument ignores an important difference between the cited sections and § 211. Sections 108 and 202 are mandatory in their terms; under both sections the Administrator "shall" regulate if "in his judgment" the pollutants warrant regulation. Because of the mandatory nature of the provisions, express provision for administrative discretion via the "judgment" phrase is necessary. By contrast, § 211 is permissive; the Administrator "may" regulate if emissions "will endanger"

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Originally, it is true, it appeared that Congress would severely restrict the Administrator's ability to assess risks and make policy judgments to protect public health. The bill sent to the floor of the House, and eventually passed by the House, would have allowed EPA to control fuels or fuel additives only if the determination that their emission products would endanger the public health were established

> on the basis of *specific findings* derived from relevant medical and scientific evidence, including * * * a *finding* that it is not otherwise technologically or economically feasible to achieve the emission standards established pursuant to section 202 of this Act.

H.R. 17255, 91st Cong., 2d Sess. § 210(g)(1) (1970) (emphasis added). The specific findings requirement had more than procedural significance. It limited the scope of evidence on which the Administrator could proceed, made alternative action under Section 202 mandatory if possible, and was widely interpreted in the House, as the extracts of debate relied upon by petitioners show, Ethyl Supp. Br. at 24; NPRA Supp. Br. at 30; Nalco Supp. Br. at 15, as requiring that any EPA action be

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the public health. Since discretion is provided in the directive to the Administrator, the safety valve of a "judgment" phrase is unnecessary. On the other hand, since we find the exercise of judgment to be implicit in a determination of "danger," there is no need for an express statement of that power and no reason to ascribe significance to the omission of the phrase.

The irrelevancy of the omission is shown by the *Amoco* decision, where the court construed § 211(c)(1)(B), which, like its sister section at issue here, does not contain the phrase "in his judgment." Nonetheless, the court recognized the Administrator must, necessarily, have the power to assess risks and make policy decisions under that section whenever the determinations called for are judgmental. *Amoco Oil Co.* v. *EPA*, *supra* note 2, 163 U.S.App.D.C. at 180-181, 501 F.2d at 740-741, *quoted in* text at pp. 43-44 *infra*.

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based solely on facts.[38] *See also* H.R. Rep. No. 91-1146, 91st Cong., 2d Sess., at 13 (1970).

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[38] Petitioner Nalco argues that if the specific requirement, and its subsequent deletion, have substantive effect at all, that effect relates not to the threshold decision to regulate, but to the subsequent implementing decisions about how to regulate. Nalco Supp. Br. at 17-20. It is true that a literal reading of the House version, proposed § 210(g)(1), suggests that specific findings are required in setting "standards" for fuel additives rather than for the threshold decision to regulate. Nonetheless, it is doubtful that the language was intended to exempt the threshold decision to regulate from the specific findings requirement, and equally doubtful that a court would ever have so interpreted it. First, as a practical matter it is questionable whether specific findings on "standard" setting could be made without a specific finding as to danger. The threshold finding would seem to be a prerequisite to any subsequent specific findings. Second, the legislative history makes it clear that the House intended the specific findings requirement to apply to the threshold regulatory decision. In presenting the proposed bill to that chamber Rep. Staggers, chairman of the committee that drafted the bill, was confronted with questions about the basis on which the Administrator could regulate fuel additives. Rep. Staggers responded that the Administrator could regulate only "[i]f he has the facts, and he has proven this by facts, that they are a danger and poisonous * * *." 116 CONG. REC. 19229 (1970). To confirm that regulation could proceed only upon a threshold factual determination of danger, Rep. Staggers then quoted the specific findings provision that Nalco now argues is inapplicable to this question. *Id.* at 19230. Likewise, Rep. Rogers, a member of Rep. Staggers' committee, made clear that the threshold determination—that the gasoline additive endangers health—must be made on the basis of facts and findings. *Id.* at 19231. These are the only specific comments on proposed § 210(g)(1), and as they are made by knowledgeable committee members the legislative history is clear that specific findings were intended for the threshold decision to regulate.

This conclusion is bolstered by § 211(c)(1)(B) and its interpretation by the *Amoco* court. Section 211(c)(1)(B), unlike § 211(c)(1)(A), retains the finding requirement and

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But the House bill did *not* become law. The Senate's preference for less restriction of EPA freedom in regulating fuel additives for health reasons [39] was adopted

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the requirement is phrased as ambiguously as the specific findings requirement in the House version of § 211(c)(1)(A). The *Amoco* court recognized that a literal reading of this findings requirement (which it termed "awkwardly drafted," *Amoco Oil Co.* v. *EPA*, *supra* note 2, 163 U.S.App. D.C. at 179, 501 F.2d at 739), would produce an anomalous result, just as the literal reading now urged by Nalco of the deleted findings requirement would produce an anomalous result. "Thus in a literal sense the provision requires 'findings with respect to' the *actual items of data* which the Administrator must 'consider.'" *Id.*, 163 U.S.App.D.C. at 176, 501 F.2d at 736 (emphasis in original). The court rejected this literal, nonsensical, reading and instead read the statute to require a threshold factual finding that regulation was necessary under § 211(c)(1)(B). *Id.*, 163 U.S.App.D.C. at 176-178, 501 F.2d at 736-738.

Based on the legislative history of the House proposed § 210(g) and the *Amoco* precedent relating to the parallel section, it is clear that had the proposed specific findings requirement been enacted into law, it would have been interpreted, as suggested in the text, as requiring a specific factual finding for the threshold decision to regulate, and not necessarily specific findings for all the subsequent implementing decisions.

[39] The original Senate version of the bill provided:

> The Secretary may from time to time on the basis of information obtained under subsection (b) of this section [which required fuel manufacturers to furnish various information to the Secretary] or other information available to him, by regulation control or prohibit the introduction into commerce of any fuel or fuels for use in vehicle engines if the combustion or evaporation of such fuel produces emissions which endanger the public health or welfare * * *.

S. 4358, § 212(c)(1), 91st Cong., 2d Sess. (1970). The Senate bill drew a distinction between regulation on public health and public welfare grounds and required that regulation for the latter reason be preceded by public hearings. *Id.* § 212(c)(2). With minor verbal changes and deletion of the

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by the conference committee and ultimately enacted into law.[40] Although the legislative history does not expressly

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health-welfare dichotomy the Senate version became § 211 (c) (1).

Petitioners argue that the Senate as well as the House contemplated a factual threshold determination. Nalco Supp. Br. at 15-16; Ethyl Supp. Br. at 24-26; NPRA Supp. Br. at 30. Their arguments are without merit. While the House debate contains several references to the need for such a determination, always coupled with discussion of the "specific findings" requirement, *see* notes 38 *supra* and 40 *infra*, petitioners can point to *no* express reference in the Senate proceedings to the need for a factual threshold finding. Instead they identify discussions of danger and suggest that these somehow imply that the assessment of danger be factually based. The implication is nonsensical; the cited discussions do no more than reiterate the language of the statute, which does not in terms require a factual finding. *See* S. Rep. No. 91-1196, 91st Cong., 2d Sess. 117 (1970) ("if the combustion or evaporation of such fuel produces emissions which endanger the public health or welfare"); *id.* at 33-34 ("emission that is a direct endangerment to the public health") (*see* notes 25 & 36 *supra*); 116 CONG. REC. 32921 (1970) (statement of Sen. Baker) ("emissions that, in and of themselves, endanger the public health or welfare") (*see* page 58 *infra*). When compared with the explicit House discussion of the need for a factual finding, these statements only show that the Senate intended no such thing. Ethyl also cites this excerpt from the Senate Report:

> "The [Administrator] may prohibit the use of any fuel in commerce which may provide emissions that, *he finds*, would endanger the public health." Sen. Rep. No. 91-1196, 91st Cong., 2d Sess. 64 (1970).

Ethyl Supp. Br. at 25 (emphasis in original). Since the Senate bill explicitly deleted the finding requirement for action under § 211 (c) (1) (A), this language can hardly be taken as supporting its *sub silentio* inclusion. If anything, the language, which uses "finds" in its colloquial, not legal, sense, only demonstrates the judgmental nature of the Administrator's decision. *See* note 37 *supra*.

[40] For this reason, statements made in the House about the bill should be used only with great care in any attempt to

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discuss the reasons for the change,[41] the contrast in language is stark. As Section 211 now reads, the only "finding" the Administrator is required to make is that any fuel additive that might replace one that is prohibited does not cause emissions that will pose the same or greater danger to the public health.[42] The substantive

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assess legislative intent. House discussion centered on a significantly more rigorous bill, and statements such as those offered by petitioners from the House debate prove only the effect of the ultimate deletion of the "specific findings" requirement. *See* Ethyl Supp. Br. at 24; Nalco Supp. Br. at 15; NPRA Supp. Br. at 30. Rep. Staggers' statement, for instance, directly relates the need for a factual threshold determination to the "specific findings" requirement. As such, it is strong support for the conclusion that deletion of the requirement was intended to do away with such a rigorous threshold requirement. *See* note 38 *supra*.

[41] Neither the House managers' conference report nor the summary of the conference agreement prepared for the Senate address directly the effect of the changes here at issue. *See* Conference Agreement on the Clean Air Amendments of 1970, H.R. Rep. No. 91-1783, 91st Cong., 2d Sess. 52-53 (1970); Summary of the Provisions of Conference Agreement on the Clean Air Amendments of 1970, 116 CONG. REC. 42384, 42385-42386 (1970). The most relevant discussion, which is only oblique, is in the Senate conference report, where the need for flexibility in applying § 211 is made clear:

> [T]he conference committee wishes to call the attention of the Administrator to the broad environmental, esthetic and health considerations underlying the enactment of this legislation which should be kept in mind in making these determinations [to control or prohibit a fuel or fuel additive].

116 CONG. REC. 42386 (1970). *See Amoco Oil Co.* v. *EPA*, *supra* note 2, 163 U.S.App.D.C. at 173-174, 501 F.2d at 733-734. In the absence of legislative history discussing the change, we must rely on the language of the present law and its contrast to the rejected House version.

[42] Section 211(c)(2)(C), 42 U.S.C. § 1857f-6c(c)(2)(C), *quoted in* text at p. 64 *infra*.

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impact of the change is clear. All of the requirements for specific findings quoted above are replaced by requirements that the Administrator "consider" the specified evidence. The mandatory deference to Section 202 is removed.[43] And the Administrator may act based on all information available to him.[44] As we recognized in *Amoco*, construing a similar change in parallel Section 211(c)(1)(B), the conference committee's decision "was a deliberated one and was meant to have significance." *Amoco Oil Co.* v. *EPA*, *supra*, 163 U.S.App.D.C. at 173, 501 F.2d at 733.

In this case the decision has even more significance than it did in *Amoco*, for under Section 211(c)(1)(B), at issue in *Amoco*, the Administrator was still required to make "findings." All the conferees dropped was the adjective "specific." For regulation under Section 211(c)(1)(A), at issue here, however, *the entire requirement was dropped*, and no greater restriction was placed on the Administrator than that required by the "basis and purpose" statement of Section 4(b) of the APA, 5 U.S.C. § 553(c). We interpreted the meaning of the limited findings requirement for acting under Section 211(c)(1)(B) in *Amoco*:

> [W]e read Section 211(c)(2)(B) as incorporating the commonsense approach which the courts have

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[43] *See* note 14 *supra*.

[44] The House bill required the Administrator to act only on the basis of the required specific findings. The Senate and final bill allows him to act on the basis of information obtained under § 211(b), which requires fuel and fuel additive manufacturers to furnish the Administrator with information about their products' content and, at his request, to conduct various tests on the compounds and furnish him with descriptions of testing techniques. The Administrator is also free to act on the basis of any "*other information available to him*," § 211(c)(1) (emphasis added), thus making the basis for action under § 211(c)(1)(A) unlimited.

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> developed in applying Section 4(b)[45] of the APA. Where EPA's regulations turn crucially on factual issues, we will demand sufficient attention to these in the statement to allow the fundamental rationality of the regulations to be ascertained. *Where, by contrast, the regulations turn on choices of policy, on an assessment of risks, or on predictions dealing with matters on the frontiers of scientific knowledge, we will demand adequate reasons and explanations, but not "findings" of the sort familiar from the world of adjudication.*

Amoco Oil Co. v. *EPA, supra,* 163 U.S.App.D.C. at 180-181, 501 F.2d at 740-741 (emphasis added). Thus the *Amoco* court read the limited findings necessary for action under Section 211(c)(1)(B) as a flexible requirement that demanded actual findings for questions of fact and something less—"adequate reasons and explanations"—for questions of policy.

As petitioners correctly point out, the *Amoco* court applied this approach by holding that the threshold determination whether to regulate at all under Section 211(c)(1)(B) was essentially a question of fact, for which a factual finding must be offered. In suggesting that such a finding is necessary for action under Section 211(c)(1)(A) as well, however, petitioners completely ignore the fact that a finding is required for action under Section 211(c)(1)(B) and is not required under Section 211(c)(1)(A). By so glossing over the language of the statute, petitioners miss a vital difference between the threshold determinations under Sections 211(c)(1)(A) and (B). Recall what the Administrator must find in order to act under Section 211

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[45] The opinion refers to § 4(c), but § 4(b), which requires the agency to "incorporate in the rules adopted a concise statement of their basis and purpose," was obviously intended. *See* § 4 of the APA, 60 STAT. 239 (1946), 5 U.S.C. § 553.

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(c)(1)(B): that the emission products of the fuel or additive to be regulated

> will impair to a significant degree the performance of any emission control device or system which is in general use, or which the Administrator finds has been developed to a point where in a reasonable time it would be in general use were such regulation to be promulgated.

42 U.S.C. § 1857f-6c(c)(1)(B). At its core, this is a peculiarly factual finding. Will the emission impair the performance of a control device? Is the device in general use, or has it the potential to be? These were the questions, highly suitable to factual proof, that the *Amoco* court construed. Contrary to petitioners' implication, the court did not hold that *any* threshold determination to regulate must be based on factual proof, but that *this* threshold determination must be factually based. The Section 211(c)(1)(A) threshold determination, however, is inherently unlike that of its sister section. "Endanger," as we have suggested above, is not a standard prone to factual proof alone. Danger is a risk, and so must be decided by assessment of risks as well as by proof of facts.

Thus a reason emerges for the deletion of the findings requirement for action under the "will endanger" standard. The *Amoco* court held the findings requirement of Section 211(c)(1)(B) no more than reiterated the minimal demands of the basis and purpose statement of the APA. *Amoco Oil Co.* v. *EPA*, *supra*, 163 U.S.App.D.C. at 179, 501 F.2d at 739. What Congress was doing, then, was using the findings requirement to indicate which section demanded a *factual* threshold determination and which section did not. While inclusion of the phrase was unnecessary in that the APA would have demanded a factual threshold determination under Section 211(c)(1)(B) in any case, the selective use of the

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findings requirement served to emphasize to the Administrator the demands of the APA and the intent of the Congress. While Congress did not discuss the extent of the Administrator's power under the "will endanger" standard, its actions—the statute it enacted and the one it rejected—make the legislative intent clear. We find that deletion of the findings requirement for action under Section 211(c)(1)(A) was a recognition by Congress that a determination of endangerment to public health is necessarily a question of policy that is to be based on an assessment of risks and that should not be bound by either the procedural or the substantive rigor proper for questions of fact.

This conclusion follows not only from the language of Section 211(c)(1)(A) and its legislative history, but from the nature of the Administrator's charge: to protect the public from danger. Regulators such as the Administrator must be accorded flexibility, a flexibility that recognizes the special judicial interest in favor of protection of the health and welfare of people, even in areas where certainty does not exist. *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 142 U.S. App.D.C. 74, 88, 439 F.2d 584, 598 (1971).

Questions involving the environment are particularly prone to uncertainty. Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown, sometimes unknowable. While a concerned Congress has passed legislation providing for protection of the public health against gross environmental modifications,[46] the regulators entrusted with the enforcement

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[46] Clean Air Act, 42 U.S.C. § 1857 *et seq.*; Federal Water Pollution Control Act, 33 U.S.C. § 1151 *et seq.*; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 135 *et seq.*

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of such laws have not thereby been endowed with a prescience that removes all doubt from their decision-making. Rather, speculation, conflicts in evidence, and theoretical extrapolation typify their every action. How else can they act, given a mandate to protect the public health but only a slight or nonexistent data base upon which to draw? Never before have massive quantities of asbestiform tailings been spewed into the water we drink.[47] Never before have our industrial workers been occupationally exposed to vinyl chloride [48] or to asbestos dust.[49] Never before has the food we eat been permeated with DDT [50] or the pesticides aldrin and dieldrin.[51] And never before have hundreds of thousands of tons of lead emissions been disgorged annually into the air we breathe. Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, "reasonable medical concerns" and theory long precede certainty. Yet the statutes—and common sense—demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

Undoubtedly, certainty is the scientific ideal—to the extent that even science can be certain of its truth.[52] But certainty in the complexities of environmental medicine may be achievable only after the fact, when scientists

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[47] *Reserve Mining Co.* v. *EPA*, *supra* note 13.

[48] *The Society of the Plastics Industry, Inc.* v. *OSHA*, *supra* note 35.

[49] *Industrial Union Department, AFL-CIO* v. *Hodgson*, *supra* note 35.

[50] *Environmental Defense Fund, Inc.* v. *EPA* (Coahoma), *supra* note 28.

[51] *Environmental Defense Fund, Inc.* v. *EPA* (Shell), 167 U.S.App.D.C. 71, 510 F.2d 1292 (1975).

[52] Even scientific "facts" are not certain, but only theories with high probabilities of validity. Scientists typically speak not of certainty, but of probability; they are trained to act

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have the opportunity for leisurely and isolated scrutiny of an entire mechanism. Awaiting certainty will often allow for only reactive, not preventive, regulation.[53] Petitioners suggest that anything less than certainty, that any speculation, is irresponsible. But when statutes seek to avoid environmental catastrophe, can preventive, albeit uncertain, decisions legitimately be so labeled?

The problems faced by EPA in deciding whether lead automotive emissions pose a threat to the public health

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on probabilities that statistically constitute "certainties." *See generally* T. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS. While awaiting such statistical certainty may constitute the typical mode of scientific behavior, its appropriateness is questionable in environmental medicine, where regulators seek to prevent harm that often cannot be labeled "certain" until after it occurs. *See* note 58 *infra*.

The uncertainty of scientific fact parallels the uncertainty of all fact. In a metaphysical sense, at least, facts are themselves nothing more than risks, or statistical probabilities. *See* D. HUME, A TREATISE OF HUMAN NATURE, bk. I, pt. III, § 6, at 87 (L.A. Selby-Bigge ed. 1958).

[53] Thus this court, per Judge Wilkey, affirmed EPA's general ban on the use of DDT even though the evidence was considerably less than certain:

> [T]here is a great mass of often inconsistent evidence which was developed at the hearing; this evidence is substantial enough to support the conclusions of the Administrator, although it possibly might support contrary conclusions as well. Considering the evidence as a whole, we cannot say that the Administrator's decision was not based on substantial evidence, *even if the hazardous nature of DDT has not been proved beyond a reasonable doubt. Sufficient evidence has been adduced to show potentially great dangers from DDT,* and the Administrator's decision to cancel the DDT registration is well within his statutory authority.

Environmental Defense Fund, Inc. v. *EPA* (Coahoma), *supra* note 28, 160 U.S.App.D.C. at 128, 489 F.2d at 1252 (emphasis added).

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highlight the limitations of awaiting certainty. First, lead concentrations are, even to date, essentially low-level, so that the feared adverse effects would not materialize until after a lifetime of exposure. Contrary to petitioners' suggestion, however, we have not yet suffered a lifetime of exposure to lead emissions. At best, emissions at present levels have been with us for no more than 15-20 years.[54] Second, lead exposure from the ambient air is pervasive, so that valid control groups cannot be found against which the effects of lead on our population can be measured. Third, the sources of human exposure to lead are multiple, so that it is difficult to isolate the effect of automobile emissions. Lastly, significant exposure to lead is toxic, so that considerations of decency and morality limit the flexibility of experiments on humans that would otherwise accelerate lead exposure from years to months, and measure those results.[55] *Cf. Environmental Defense Fund, Inc.* v. *EPA* (Shell), 167 U.S.App.D.C. 71, 78, 510 F.2d 1292, 1299 (1975).

The scientific techniques for attempting to overcome these limitations are several: toxicology can study the distribution and effect of lead in animals; epidemiological techniques can analyze the effects of lead emissions on entire populations; clinical studies can reproduce in

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[54] According to the NAS Panel, present air lead concentrations, which over the largest American cities are 2,000 times greater than air lead concentrations over the mid-Pacific Ocean, have existed for 15 years. NAS Report at 205, JA 356. The Panel attributed these high concentrations primarily to automotive emissions. *Id.*

[55] It is for these reasons that, although lead additives have been used for over 50 years, the danger posed by lead emissions is still a question "on the frontiers of scientific knowledge." *Industrial Union Department, AFL-CIO* v. *Hodgson*, *supra* note 49, 162 U.S.App.D.C. at 338, 499 F.2d at 474. *See* note 97 *infra.*

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laboratories atmospheric conditions and measure under controlled circumstances the effects on humans. All of these studies are of limited usefulness, however. Dr. J. H. Knelson, Director of EPA's Human Studies Laboratory, has described, in the context of setting ambient air standards, the limitations of these various investigative tools:

> Each of these investigative approaches—classic toxicology, epidemiology, and clinical research has its advantages and disadvantages. The toxicologist can control the dose and use invasive or destructive techniques in measuring response in the animal, but is always faced with the problem of extrapolating results to humans. Epidemiology is most relevant because it studies phenomena actually occurring in humans under "natural" conditions, but can only draw inference from observed correlations rather than prove cause and effect relationships. Clinical research can provide the most accurate dose-response relationships in the species of interest. Precisely because the study subjects are humans, however, many experimental design problems are encountered in assuring their safety. Although the dose of an atmospheric pollutant can be carefully controlled and measured in the clinical laboratory, qualitative comparability to the multiplex variable of atmospheric pollution cannot always be assured.
>
> The best scientific criteria for establishing air quality standards result from interactions between these disciplines. Clinical studies must be preceded by exhaustive toxicological assessment in other species; observations from population studies should play an important role in the experimental design of clinical research. Biomedical data from all these sources, taken in their entirety, should be used for the prudent definition of air pollution control needs.

JA 582-583. The best biomedical evidence will be derived from relating all three research approaches. This EPA did. That petitioners, and their scientists, find a

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basis to disagree is hardly surprising, since the results are still uncertain, and will be for some time. But if the statute accords the regulator flexibility to assess risks and make essentially legislative policy judgments, as we believe it does, preventive regulation based on conflicting and inconclusive evidence may be sustained. Recent cases have recognized this flexibility in similar situations.

In *Industrial Union Department, AFL-CIO* v. *Hodgson*, *supra*, this court considered the Secretary of Labor's delegated power under the Occupational Safety and Health Act (OSHA), 29 U.S.C. § 651 *et seq.*, to protect the health of industrial workers by setting standards for exposure to industrial pollutants. Under review was a standard for exposure to asbestos dust, thought to be carcinogenic. Judge McGowan, writing for the division, laid down the rule:

> From extensive and often conflicting evidence, the Secretary in this case made numerous factual determinations. With respect to some of those questions, the evidence was such that the task consisted primarily of evaluating the data and drawing conclusions from it. The court can review that data in the record and determine whether it reflects substantial support for the Secretary's findings. But some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis.[18]

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[18] Where existing methodology or research in a new era of regulations is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information, Permian Basin Area Rate Cases, 390 U.S. 747, 811, 88 S.Ct. 1344, 20 L.Ed.2d 312 (1968).

162 U.S.App.D.C. at 338, 499 F.2d at 474.

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This rule was likewise applied in *The Society of the Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975), where the Second Circuit reviewed regulations limiting industrial exposure to vinyl chloride, also considered a carcinogen:

> As in Industrial Union Department, AFL-CIO v. Hodgson, *supra*, the ultimate facts here in dispute are "on the frontiers of scientific knowledge," and, though the factual finger points, it does not conclude. Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient. The Secretary, in extrapolating the MCA study's finding from mouse to man, has chosen to reduce the permissible level to the lowest detectable one. We find no error in this respect.

Id. at 1308. And in *Reserve Mining* the Eighth Circuit agreed. Although reviewing the determination of a District Court, not an expert Administrator, the court recognized that it must nonetheless apply the test of the preventive statute before it:

> [W]e note that many of the issues in this case do not involve "historical" facts subject to the ordinary means of judicial resolution. Indeed, a number of the disputes involve conflicting theories and experimental results, about which it would be judicially presumptuous to offer conclusive findings [*quoting Amoco Oil Co.* v. *EPA*, 163 U.S.App.D.C. 181, 501 F.2d at 741, which relied on *Industrial Union*]. In such circumstances, the finder of fact must accept certain areas of uncertainty, and the findings themselves cannot extend further than attempting to assess or characterize the strengths and weaknesses of the opposing arguments.

514 F.2d at 507 n.20. *See also id.* at 529.

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These cases, recognizing as they do the developing nature of environmental medicine, fortify our analysis of the "will endanger" language of Section 211.[56] Where a statute is precautionary in nature,[57] the evidence dif-

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[56] Ethyl argues that *Industrial Union* and *Society of the Plastics Industry* are distinguishable from this case in that under OSHA the Secretary is *directed* to set standards for industrial exposure to toxic substances, 29 U.S.C. § 655(b)(5), while action under § 211 is discretionary with the Administrator. Ethyl Supp. Br. at 28-30. Ethyl has merely identified the source of the flexibility granted the Secretary, while failing to set the cited cases apart from this one. Under the Clean Air Act the Administrator's flexibility is derived not from a command to act, but from a precautionary statute that necessarily includes risk assessment if its preventive purpose is to be achieved. Since there is reason to accord flexibility to the regulator under both acts, the cited cases are good support for the way in which that flexibility is to be exercised.

Nalco asserts that the cases are distinguishable in that *Industrial Union* and *Society of the Plastics Industry* involve the manner in which standards are set under OSHA, rather than the Secretary's power to set standards at all. Nalco Supp. Br. at 12. This purported distinction is no more than a factual difference between the cases. Flexibility is necessary under OSHA only in the manner of setting standards, since the command to set standards is clear. Under the Clean Air Act, on the other hand, flexibility is necessary both in standard-setting and in deciding whether to regulate. The teaching of the cases is nonetheless applicable.

Reserve Mining shows the spurious nature of both asserted distinctions. In that case, as here, there was no command to regulate, only a statutory term of a precautionary nature—"endangering"—to justify flexibile decision-making (in *Reserve Mining* by a court rather than by an agency). Likewise, that case involved not only the manner of standard-setting, but the threshold decision to regulate as well. Nonetheless, *Reserve Mining* is fully consistent with *Industrial Union* and *Society of the Plastics Industry*, and all three cases support our conclusion here.

[57] Or, as with OSHA, mandatory in its command to act. *See* note 56 *supra*.

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ficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served. Of course, we are not suggesting that the Administrator has the power to act on hunches or wild guesses. *Amoco* makes it quite clear that his conclusions must be rationally justified. *Amoco Oil Co.* v. *EPA*, *supra*, 163 U.S.App.D.C. at 180-181, 501 F.2d at 740-741. However, we do hold that in such cases the Administrator may assess risks. He must take account of available facts, of course, but his inquiry does not end there. The Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as "fact," and the like. We believe that a conclusion so drawn—a risk assessment—may, if rational, form the basis for health-related regulations under the "will endanger" language of Section 211.[58]

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[58] It bears emphasis that what is herein described as "assessment of risk" is neither unprecedented nor unique to this area of law. To the contrary, assessment of risk is a normal part of judicial and administrative fact-finding. Thus EPA is not attempting to expand its powers; rather, petitioners seek to constrict the usual flexibility of the fact-finding process. Petitioners argue that the Administrator must decide that lead emissions "will endanger" the public health solely on "facts," or, in the words of the division majority, by a "chain of scientific facts or reasoning leading [the Administrator] ineluctably to this conclusion * * *." Division op. at 59. Petitioners demand sole reliance on *scientific* facts, on evidence that reputable scientific techniques certify as certain. Typically, a scientist will not so certify evidence unless the prob-

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All of this is not to say that Congress left the Administrator free to set policy on his own terms. To the contrary, the policy guidelines are largely set, both in the statutory term "will endanger" and in the relation-

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ability of error, by standard statistical measurement, is less than 5%. That is, scientific fact is at least 95% certain.

Such certainty has never characterized the judicial or the administrative process. It may be that the "beyond a reasonable doubt" standard of criminal law demands 95% certainty. *Cf. McGill* v. *United States*, 121 U.S.App.D.C. 179, 185 n.6, 348 F.2d 791, 797 n.6 (1965). But the standard of ordinary civil litigation, a preponderance of the evidence, demands only 51% certainty. A jury may weigh conflicting evidence and certify as adjudicative (although not scientific) fact that which it believes is more likely than not. Since *Reserve Mining* was adjudicated in court, this standard applied to the court's fact-finding. Inherently, such a standard is flexible; inherently, it allows the fact-finder to assess risks, to measure probabilities, to make subjective judgments. Nonetheless, the ultimate finding will be treated, at law, as fact and will be affirmed if based on substantial evidence, or, if made by a judge, not clearly erroneous.

The standard before administrative agencies is no less flexible. Agencies are not limited to scientific fact, to 95% certainties. Rather, they have at least the same fact-finding powers as a jury, particularly when, as here, they are engaged in rule-making.

> Looking to the future, and commanded by Congress to make policy, a rule-making agency necessarily deals less with "evidentiary" disputes than with normative conflicts, projections from imperfect data, experiments and simulations, educated predictions, differing assessments of possible risks, and the like.

Amoco Oil Co. v. *EPA*, *supra* note 2, 163 U.S.App.D.C. at 175, 501 F.2d at 735. An agency's finding of fact differs from that of a jury or trial judge primarily in that it is accorded more deference by a reviewing court. *See* note 74 *infra*. Thus, as a matter of administrative law, the Administrator found *as fact* that lead emissions "will endanger" the public health. That in so doing he did not have to rely solely on proved

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ship of that term to other sections of the Clean Air Act. These prescriptions direct the Administrator's actions. Operating within the prescribed guidelines, he must consider all the information available to him. Some of the information will be factual, but much of it will be more speculative—scientific estimates and "guesstimates" of probable harm, hypotheses based on still-developing data, etc. Ultimately he must act, in part on "factual issues," but largely "on choices of policy, on an assessment of risks, [and] on predictions dealing with matters on the frontiers of scientific knowledge * * *." *Amoco Oil Co.* v. *EPA*, *supra*, 163 U.S.App.D.C. at 181, 501 F.2d at 741. A standard of danger—fear of uncertain or unknown harm—contemplates no more.

3. *Propriety of the Cumulative Impact Approach.* In addition to demanding that the Administrator act solely on facts, petitioner Ethyl insists that those facts convince him that the emission product of the additive to be regulated "in and of itself," *i.e.*, considered in isolation, endangers health. The Administrator contends that the impact of lead emissions is properly considered together with all other human exposure to lead. *See* page 18 *supra*. We agree.

First, Ethyl points to the language of Section 202 allowing regulation of any automobile emission that "causes or *contributes to*, or is likely to cause or *con-*

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scientific fact is inherent in the requirements of legal fact-finding. Petitioners' assertions of the need to rely on "fact" confuse the two terminologies. We must deal with the terminology of law, not science. At law, unless the administrative or judicial task is peculiarly factual in nature, or Congress expressly commands a more rigorous finding, *see* 21 U.S.C. § 355(d); *cf.* pages 43-45 *supra*, assessment of risks as herein described typifies both the administrative and the judicial fact-finding function, and is not the novel or unprecedented theory that petitioners contend.

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tribute to, air pollution which endangers the public health or welfare." Section 202(a)(1), 42 U.S.C. § 1857 f-1(a)(1) (emphasis Ethyl's in its brief at 18). This is contrasted with Section 211's language allowing regulation of fuels or fuel additives whose "emission products * * * will endanger the public health or welfare." By italicizing the "contribute to" language of Section 202 Ethyl presumably suggests that Section 202 is more lenient, allowing use of the cumulative impact theory while Section 211 does not. This argument is but a variant on Ethyl's already rejected claim that Section 202 allows for regulation of "likely" dangers while Section 211 does not. As with the earlier argument, this reading of Section 202 must be rejected. While it is possible that Section 202's inclusion of emissions that "cause or contribute to air pollution" is more encompassing than Section 211's term "emission products," it is clear that whatever leniency Section 202 suggests only concerns the makeup of air pollution. This is irrelevant to the cumulative impact theory. However they differ, both Section 202 and Section 211 allow regulation of lead additives only on a determination that the resultant polluted air, however composed, endangers the public health.[59] Both provisions leave open the question

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[59] As far as the cumulative impact theory is concerned, the relevant portions of the two provisions are as follows:

> [The Administrator may regulate any automobile emission that] causes or contributes to, or is likely to cause or contribute to, *air pollution which endangers the public health or welfare.*

Section 202(a)(1), 42 U.S.C. § 1857f-1(a)(1) (emphasis added).

> [The Administrator may regulate a fuel or fuel additive] *if any emission products* of such fuel or fuel additive *will endanger the public health or welfare* * * *.

Section 211(c)(1)(A), 42 U.S.C. § 1857f-6c(c)(1)(A) (emphasis added).

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whether emissions or air pollution can be found to endanger the public health when the endangerment is not caused by that pollution alone.[60]

While Ethyl's comparison suggests no answer, the question is directly raised here. The Administrator found endangerment, but recognized that the national lead exposure problem is caused, not by air pollution alone, but by an aggregate of sources, including food, water, leaded paint, and dust. He believed that regulation was justified because the aggregate was dangerous, and because leaded gasoline was a *significant* source that was particularly suited to ready reduction. 38 FED. REG. 33734. To the question whether the Administrator was correct in his belief, comparison with the "contribute to" language of Section 202 provides no guidance.

The only other evidence relied upon by Ethyl for its "in and of itself" theory is a quotation, taken out of context, from Senator Baker. When the context of Ethyl's partial quotation is revealed the irrelevance of his statement to Ethyl's theory becomes clear. Senator Baker reviewed the Committee bill for the Senate:

> The [Administrator] is authorized to either control or prohibit the sale of any given fuel when he finds one of two things:
>
> First. That the combustion or evaporation of such fuel produces emissions that, *in and of themselves*, endanger the public health or welfare; or
>
> Second. That such emissions prevent the operation of a system that is necessary to reduce automo-

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[60] Since automobile emissions generate approximately 90% of all airborne lead, *see* note 7 *supra* and accompanying text, the danger posed by lead-polluted air is virtually identical to that posed by lead automobile emissions. As the text suggests, the non-automotive sources of lead with which the cumulative impact theory is concerned are not airborne.

> bile emissions to the levels required by standards issued by the [Administrator] under section 202 of the act.

116 CONG. REC. 32920 (1970) (emphasis added). Ethyl relies on the Senator's subsequent repetition of the words "in and of themselves," italicized above. Ethyl brief at 16. But the second paragraph makes clear that Senator Baker's meaning is contrary to Ethyl's implication. He is simply emphasizing the different nature of the two provisions and thus uses the words "in and of themselves" to show that under Section 211(c)(1)(A) the Administrator may act only because of the *direct* effects of lead additives on a legislative goal, protection of health, while under Section 211(c)(1)(B) he may act because of their *indirect* effects on another goal, implementation of emission control systems.[61]

Beyond these two points, Ethyl has nothing more to offer in support of its "in and of itself" reading. Thus it has made out no case at all, particularly in light of the realities of human exposure to lead and what Congress knew about those realities. Such consideration demonstrates both that, under Ethyl's approach, EPA regulation of lead on health grounds would be impossible and that Congress could not possibly have intended the restrictive "by itself" reading. As has been discussed more extensively above, *see* pages 10-12 *supra*, lead enters the human body from multiple sources, so that the effect

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[61] Ethyl actually quotes Sen. Baker's second use of the phrase, a few sentences after the one quoted in the text, *see* 116 CONG. REC. 32920 (1970). It, however, is in the same context of contrasting permissible EPA action under §§ 211(c)(1)(A) and (B), and thus provides no more support for Ethyl's position. The implausibility of Ethyl's reading of Sen. Baker's words is heightened by the fact that the Senator himself realized the important contribution of dietary lead to the total body lead burden and so informed the Senate only sentences before the quoted language. *Id.*

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of any one source is meaningful only in cumulative terms. If, for example, airborne lead were the only source of the lead body burden, and it caused, by itself, a blood lead level of 30 ug, there would be no danger to the public health. But if that hypothetical 30 ug is added to a possible 30 ug attributable to dietary ingestion, the blood lead level would be 60 ug, a definite threat to health. Under Ethyl's approach, despite obvious endangerment such a cumulative finding is insufficient to justify regulation. Airborne lead, in and of itself, may not be a threat. But the realities of human lead exposure show that no one source *in and of itself* (except possibly leaded paint) is a threat. Thus, under Ethyl's tunnel-like reasoning, even if parallel legislation permitted regulation of other sources of lead exposure, which it does not, no regulation could ever be justified.

Such cannot be the case. Congress understood that the body lead burden is caused by multiple sources. It understood that determining the effect of lead automobile emissions, by themselves, on human health is of no more practical value than finding the incremental effect on health of the fifteenth sleeping pill swallowed by a would-be suicide.[62] It did not mean for "endanger" to be measured only in incremental terms.[63] This the Ad-

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[62] While the incremental effect of lead emissions on the total body lead burden is of no practical value in determining whether health is endangered, it is of value, of course, in deciding whether the lead exposure problem can fruitfully be attacked through control of lead additives. Moreover, even under the cumulative impact theory emissions must make more than a minimal contribution to total exposure in order to justify regulation under § 211(c)(1)(A). We accept the Administrator's determination that the contribution must be "significant" before regulation is proper. *See* 38 FED. REG. 33734.

[63] Congress had before it a complete explanation of the multiple sources of human lead exposure. It understood that

ministrator also understood. He determined that absorption of lead automobile emissions, when added to all other human exposure to lead, raises the body lead burden to a level that will endanger health. He realized that lead automobile emissions were, far and away, the most readily reduced significant source of environmental lead. And he determined that the statute authorized him to reduce those emissions on such a finding. We find no error in the Administrator's use of the cumulative impact approach.

4. *Summary of the "Will Endanger" Determination.* In sum, we must reject petitioners' cramped and unrealistic interpretation of Section 211(c)(1)(A). Their reading would render the statute largely useless as a basis for health-related regulation of lead emissions. Petitioners' arguments are rebuffed by the plain meaning of the statute and the Administrator's interpretation of it,[64] by the legislative history and the implications

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lead is ubiquitous in nature, that trace elements of lead are present in everyone, and that only when lead concentration reaches higher levels would the public be endangered. It could not have thought that lead automobile emissions could, by themselves, endanger the public, although it clearly did think they could be regulated only if they provided a significant increment to the total human lead burden. *See, e.g.*, Hearings on S. 3229, S. 2466 & S. 3546 before the Subcommittee on Air & Water Pollution of the Senate Committee on Public Works, 91st Cong., 2d Sess., pt. 1, at 433-434 (1970) (answers to Sen. Muskie's questions, supplied by the Dept. of Health, Education & Welfare); *id.*, pt. 3, at 1177; 116 CONG. REC. 32920 (1970) (remarks of Sen. Baker).

[64] Considerable deference is owed to the interpretation of a statute by the officer charged with its administration. *Train* v. *Natural Resources Defense Council, Inc.*, 421 U.S. 60, 87 (1975) (Clean Air Act); *Zuber* v. *Allen*, 396 U.S. 168, 192 (1969); *Udall* v. *Tallman*, 380 U.S. 1, 16 (1965); *United States* v. *American Trucking Assns*, 310 U.S. 534, 549 (1940). This deference is heightened when, as here, the interpreta-

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that can be drawn from other sections of the same statute, by the relevant precedents, and by the established maxim that health-related legislation is liberally construed to achieve its purpose.[65]

We believe the Administrator may regulate lead additives under Section 211(c)(1)(A) when he determines, based on his assessment of the risks as developed by consideration of all the information available to him, and as guided by the policy judgment inherent in the statute, that lead automobile emissions significantly increase the total human exposure to lead so as to cause a significant risk of harm to the public health. Before so regulating, he must consider the possibility of regulation under Section 202.[66] This interpretation of Section

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tion is of a new statute by its implementing agency. *Power Reactor Development Co.* v. *International Union of Electricians*, 367 U.S. 396, 408 (1961); *United States* v. *Zucca*, 351 U.S. 91, 96 (1956); *United States* v. *American Trucking Assns, supra; Norwegian Nitrogen Products Co.* v. *United States*, 288 U.S. 294, 315 (1933); *Natural Resources Defense Council, Inc.* v. *Train*, 166 U.S.App.D.C. 312, 326, 510 F.2d 692, 706 (1975) (Clean Air Act). *See* note 16 *supra*.

[65] *See, e.g., Parke* v. *Bradley*, 204 Ala. 455, 86 So. 28 (1920); *Forbes* v. *Board of Health*, 28 Fla. 26, 9 So. 862 (1891); *People ex rel. Barmore* v. *Robertson*, 302 Ill. 422, 134 N.E. 815, 22 A.L.R. 835 (1922); *Blue* v. *Beach*, 155 Ind. 121, 56 N.E. 89 (1900); *Walker* v. *Sears*, 245 Iowa 262, 61 N.W.2d 729 (1953); *State ex rel. Freeman* v. *Fadeley*, 180 Kan. 652, 308 P.2d 537, 548 (1957); *Board of Health* v. *Kollman*, 156 Ky. 351, 160 S.W. 1052 (1913); *Rock* v. *Carney*, 216 Mich. 280, 185 N.W. 798, 22 A.L.R. 1178 (1921); *State ex rel. Freeman* v. *Zimmerman*, 86 Minn. 358, 90 N.W. 783 (1902); *Crayton* v. *Larabee*, 220 N.Y. 493, 116 N.E. 355 (1917); *Salt Lake City* v. *Howe*, 37 Utah 170, 106 P. 705 (1910).

[66] The statute demands "consideration" not only of the relevant scientific and medical evidence, but also of the possibility of regulation under § 202. Section 211(c)(2)(A), 42 U.S.C. § 1857f-6c(c)(2)(A). That means, of course, no more than it says: actual good faith consideration of the specified

211 does not allow for baseless or purposeless regulation, but does grant the Administrator the flexibility needed to confront realistically the public health problem presented by massive diffusion of lead emissions from automobiles.

B. *Comparison with Substitute Additives*

Even when the Administrator has determined that a fuel or fuel additive causes emissions which endanger

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evidence and options, as reflected in the basis and purpose statement required by § 4(b) of the APA, 5 U.S.C. § 553(c). NPRA argues that the statute demands mandatory deference to the possibility of regulation under § 202 rather than mere consideration of such a possibility. NPRA Supp. Br. at 33-35. We reject the argument. NPRA ignores the deletion of the specific findings requirement from the original bill. As pointed out above, see pages 38-43 & note 14 *supra*, one effect of the deletion was to eliminate mandatory deference to § 202 and substitute instead "consideration" of § 202 regulation. While Congress thus indicated its preference for regulation under § 202, it left the Administrator with full discretion to implement that preference or not. *See* note 14 *supra*.

NPRA, joined by Nalco, further argues that EPA's consideration of § 202 regulation was arbitrary and capricious because the agency rejected reliance on lead traps as a means of emission control. NPRA Supp. Br. at 35-37; Nalco Supp. Br. at 57-58. EPA did reject lead traps, but that rejection was not arbitrary and capricious. Rather, they were rejected because § 202 authorizes EPA to order emission controls only on *new* vehicles, which would largely be using lead-free gasoline anyway because of the catalytic converter. On new vehicles there would be no lead emissions to trap. *See* note 2 *supra*. The regulations before us seek to reduce lead emissions from in-use vehicles; for such a purpose § 202 is of no use. 38 FED. REG. 33737.

We find that EPA's consideration of the evidence presented and of the alternatives to regulation under § 211 meets the good faith test suggested above. *See Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 416 (1971). *See also* note 68 *infra*.

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the public health, he is not yet free to prohibit the substance under Section 211. He must first find, and publish his finding,

> that in his judgment such prohibition will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited.

Section 211(c)(2)(C), 42 U.S.C. § 1857f-6c(c)(2)(C).

Preliminarily it must be noted that the section requires a finding only before the Administrator "prohibits" a fuel or fuel additive under Section 211. Since the proposed regulations only "control" lead additives, the findings requirement, on its face, does not apply to the EPA action.[67] If the requirement is read to apply, however, it plainly demands no more than the findings requirement of Section 211(c)(2)(B), as construed in *Amoco*, *see* pages 43-44 *supra*. This conclusion is compelled

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[67] This distinction is not unduly technical, since § 211(c)(1) expressly allows the Administrator to "control or prohibit" while § 211(c)(2)(C), drafted contemporaneously, repeatedly indicates that a finding is required only before a fuel or fuel additive is "prohibited." Parallel §§ 211(c)(2)(A) and (B), on the other hand, also expressly apply before a fuel or fuel additive may be "controlled or prohibited."

Nonetheless, the purpose behind § 211(c)(2)(C)—avoidance of counterproductive results and protection of the public health—suggests that a finding is of equal import whether the fuel or fuel additive is to be controlled or prohibited, so we do not conclude definitely that no such finding is required for control under § 211. Since the Administrator has furnished a finding such as is required by § 211(c)(2)(C), 38 FED. REG. 33737-33739 (1973), and we think that finding is adequate under the *Amoco* standards suggested below, we do not find it necessary to determine whether the finding was required in this case. *See* note 68 *infra*.

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by the identical genesis of the two provisions, plus the fact that the Section 211(c)(2)(C) finding is judgmental by its own terms. Thus where the judgment turns "on factual issues" we will "demand sufficient attention to these in the statement to allow the fundamental rationality * * * to be ascertained." *Amoco Oil Co.* v. *EPA*, *supra*, 163 U.S.App.D.C. at 180-181, 501 F.2d at 740-741. By contrast, where the judgment is necessarily more speculative, we will "demand adequate reasons and explanations, but not 'findings' of the sort familiar from the world of adjudication." *Id.*, 163 U.S.App.D.C. at 181, 501 F.2d at 741.[68]

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[68] Nalco argues that the Administrator's recent decision to suspend the 1977 statutory emission standards for hydrocarbons and carbonmonoxide, 40 FED. REG. 11900, *see* note 2 *supra*, invalidates his assessment of the impact of the substitute additive, aromatic hydrocarbons. Nalco Supp. Br. at 45-50. *Cf.* NPRA Supp. Br. at 48-49. This argument appears to be a challenge to the regulations based on new information. Such challenges are cognizable under § 307 of the Clean Air Act, 42 U.S.C. § 1857h-5(b)(1), but may be brought to this court only after a preliminary presentment of the new information and a request for action to the agency. *Oljato Chapter of Navajo Tribe* v. *Train*, —— U.S.App.D.C. ——, ——, 515 F.2d 654, 666-667 (1975). Since Nalco has not complied with the rule of *Oljato Chapter*, this new information claim does not appear to be properly before us.

In any case, however, Nalco's claim is without merit. Undoubtedly high octane aromatic hydrocarbons will be used to compensate for the reduction in lead caused by the regulations and the average aromatic content of gasoline will rise from 22% to 29% (this increase includes that attributable to the lead-free regulations at issue in *Amoco*). Aromatics can result in emissions of polynuclear aromatic (PNA) hydrocarbons, some of which are carcinogenic.

Nonetheless, the Administrator determined that substitution of PNA emissions for lead emissions would be less dangerous to the public health because: (1) PNA emissions from automobiles, together with emissions from refineries that produce gasoline, account for only approximately 2% of PNA emis-

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After making the "will endanger" determination and the "substitute additives" finding, EPA has complied with the statutory mandate and is free to regulate the fuel or fuel additive under Section 211.

III. The Evidence

A. *The Standard of Review*

In promulgating the low-lead regulations under Section 211, EPA engaged in informal rule-making. As such, since the statute does not indicate otherwise, its proce-

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sions in the ambient air; (2) PNA emissions are being reduced from automobiles by the applicable hydrocarbon standards; and (3) PNA automobile emissions will continue to *decrease* overall, even while the hydrocarbon content of gasoline *increases*, as uncontrolled automobiles are retired and replaced by those with emission control systems. 38 FED. REG. 33738. Thus the Administrator concluded that replacement of lead additives by increased hydrocarbons would result only in a slight slowing of the rate of *decrease* of PNA emissions from automobiles. We think this is a sufficient finding under § 211(c)(2)(C).

Nalco's charge that suspension of emission standards changes this calculation is untrue. Even under the suspended standards, hydrocarbons will be significantly controlled and PNA emissions will continue to decrease. EPA calculated the effect of an increase in hydrocarbon content of gasoline under several anticipated circumstances, including the assumption that the interim standards would remain in effect through 1980. In that circumstance, which may turn out to be the correct forecast, PNA emissions would still *decrease* 69% over 1973 levels by 1980. Without the low-lead regulations they would decrease 72%, only a 3% better rate. JA 1428-1431; *see also id.* 1489-1490. Thus EPA anticipated the possibility of suspended emission standards, calculated the effects of that suspension on PNA emissions, and found them to be minimal. We cannot find this substitute additive finding to be insufficient.

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dures are conducted pursuant to Section 4 of the APA,[69] 5 U.S.C. § 553, and must be reviewed under Section 10 of the Act,[70] 5 U.S.C. § 706(2)(A)-(D). Our review of the evidence is governed by Section 10(e)(2)(A), which requires us to strike "agency action, findings, and conclusions" that we find to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law * * *."[71] 5 U.S.C. § 706(2)(A). This standard of

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[69] The hybrid procedures that placed the EPA action somewhere between informal rule-making and adjudication and that caused such extended inquiry by the *Amoco* court are largely absent from this case. In *Amoco*, in addition to the "findings" requirement of § 211(c)(2)(B), the court had to deal with the same section's requirement of a public hearing. The resultant standard of review was, nonetheless, not significantly different from traditional "arbitrary and capricious" review. *See Amoco Oil Co.* v. *EPA*, *supra* note 2, 163 U.S.App.D.C. at 171-181, 501 F.2d at 731-741. In this case there is no public hearing requirement and the only "findings" requirement is that of § 211(c)(2)(C), which we have construed at pp. 63-66 *supra*.

The requirement that the Administrator "consider" various evidence before acting under § 211(c)(1)(A) guides the direction, but does not affect the rigor, of "arbitrary and capricious" review. Such guidelines are typical as a prerequisite for agency action, *see, e.g.*, § 1002(e) (the Rule of Ratemaking) of the Federal Aviation Act of 1958, 49 U.S.C. § 1482(e) (1970), and assurance of agency compliance is simply one part of "arbitrary and capricious" review. *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 416 (1971) (court must determine "whether the decision was based on a consideration of the relevant factors").

[70] All the Clean Air Act says about judicial review of EPA action under § 211 is that it shall be available exclusively in this court. 42 U.S.C. § 1857h-5(b)(1).

[71] Our review of the Administrator's construction of the statute, *see* pages 16-66 *supra*, is authorized by § 10(e)(2)(C), 5 U.S.C. § 706(2)(C), which allows the reviewing court to set aside agency action it finds to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory

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review is a highly deferential one. It presumes agency action to be valid. *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 415 (1971); *Pacific States Box & Basket Co.* v. *White*, 296 U.S. 176, 185-186 (1935); *United States* v. *Chemical Foundation*, 272 U.S. 1, 14-15 (1926).[72] Moreover, it forbids the court's substituting its judgment for that of the agency, *Citizens to Preserve Overton Park* v. *Volpe*, *supra*, 401 U.S. at 416, and requires affirmance if a rational basis exists for the agency's decision.[73] *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 290 (1974). *Cf. United States* v. *Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 749 (1972).

This is not to say, however, that we must rubber-stamp the agency decision as correct. To do so would render the appellate process a superfluous (although time-consuming) ritual. Rather, the reviewing court must assure itself that the agency decision was "based on

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right * * *." Our review of EPA procedures, *see* pages 97-111 *infra*, is pursuant to § 10(e)(2)(D), 5 U.S.C. § 706(2)(D), which authorizes reversal of agency action taken "without observance of procedure required by law."

[72] NPRA seeks to attach meaning to the fact that an express presumption of validity was included in the Senate version of the Clean Air Act, and then deleted by the conference committee. NPRA Supp. Br. at 21-24. *See* S. Rep. No. 91-1196, 91st Cong., 2d Sess. at 41, 125 (1970). As the above cited cases make clear, however, a general presumption of validity attaches to any regulation within an agency's delegated powers. Thus the deletion is of no consequence.

[73] Of course, that basis must be expressed by the agency itself and not supplied by the court. *SEC* v. *Chenery Corp.*, 332 U.S. 194, 196 (1947). Nonetheless, a decision of "less than ideal clarity" will be upheld if the agency's rationale "may reasonably be discerned." *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 286 (1974). *See also Colorado Interstate Gas Co.* v. *FPC*, 324 U.S. 581, 595 (1945).

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consideration of the relevant factors * * *." [74] More-

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[74] *Overton Park* also requires the reviewing court to consider "whether there has been a clear error of judgment." *Citizens to Preserve Overton Park* v. *Volpe*, *supra* note 69, 401 U.S. at 416, *citing* L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 182 (1965); *McBee* v. *Bomar*, 296 F.2d 235, 237 (6th Cir. 1961); *In re Josephson*, 218 F.2d 174, 182 (1st Cir. 1954); *Western Addition Community Organization* v. *Weaver*, 294 F.Supp. 433 (N.D. Cal. 1968); *Wong Wing Hang* v. *INS*, 360 F.2d 715, 719, (2d Cir. 1966). While as used, carefully bracketed by traditional statements of the restraint of "arbitrary and capricious" review, the phrase works no change in the law, the Court's choice of language is troublesome. The phrase sounds much like the "clearly erroneous" standard used to review the factual findings of a trial court sitting without a jury. Rule 52(a), FED. R. CIV. P. Unlike an agency determination or a jury verdict, such findings may be fairly readily reversed. *District of Columbia* v. *Pace*, 320 U.S. 698, 702 (1944); 4 K. DAVIS, *supra* note 15, § 29.02, at 118-126; L. JAFFE, *supra*, at 615-616. *See especially Orvis* v. *Higgins*, 180 F.2d 537, 540 (2d Cir.) (Frank, J.), *cert. denied*, 340 U.S. 810 (1950). Indeed, under "clearly erroneous" review a court may substitute its judgment for that of the trial court and upset findings that are not unreasonable. *See* 4 K. DAVIS, *supra* note 15, at 121-122.

Since *Overton Park* expressly forbade such intrusive review, 401 U.S. at 416, it plainly did not intend to use the "clear error of judgment" phrase to replace *sub silentio* "arbitrary and capricious" review with "clearly erroneous" review. Nonetheless, more than linguistic echoes of "clearly erroneous" review accompany the Court's turn of phrase. To the extent the cases relied upon by the Court support consideration of "clear errors of judgment," they all involve review of trial courts', and not agencies', abuses of discretion. *See* cases cited *supra*, and *compare* L. JAFFE, *supra*, at 182 *with id.* at 615-616. Such review is intrusive and essentially identical with "clearly erroneous" review. *See McBee* v. *Bomar*, *supra*; *In re Josephson*, *supra*. On the other hand, the Court also cited a case in which Judge Friendly recognized that an agency's abuse of discretion, unlike a court's, is reviewed under the "arbitrary and capricious" standard, 5 U.S.C. § 706(2)(A), and that review in such cases should be much

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over, it must engage in a "substantial inquiry" into the facts, one that is "searching and careful." *Citizens to Preserve Overton Park* v. *Volpe*, *supra*, 401 U.S. at 415,

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more deferential than under the "clearly erroneous" standard. *Wong Wing Hang* v. *INS*, *supra*, 360 F.2d at 718-719.

All of this makes the Court's intent in *Overton Park* somewhat difficult to plumb and its standard even more uncertain of application. We do not think the Court's use of the "clear error of judgment" phrase was an attempt vastly to revamp traditional "arbitrary and capricious" review. *See infra*. Nonetheless, we fear, its use of this phrase so familiar to judges in another, and significantly more intrusive, context may unintentionally prompt judicial distortion of the "arbitrary and capricious" standard. Already at least one court has expressly indicated that it is prepared to read the Court's use of the phrase as approval of intrusive "clearly erroneous" review of agency action. *Raitport* v. *National Bureau of Standards*, 385 F.Supp. 1221, 1225 (E.D. Pa. 1974). Meanwhile, other courts use the "clear error of judgment" phrase as a shorthand summary of "arbitrary and capricious" review, *see, e.g., Union Electric Co.* v. *EPA*, 515 F.2d 206, 216 (8th Cir.), *cert. granted*, —— U.S. ——, 44 U.S. L. WEEK 3200 (Oct. 6, 1975); *Conservation Council of North Carolina* v. *Froehlke*, 473 F.2d 664, 665 (4th Cir. 1973); *Schicke* v. *United States*, 346 F.Supp. 417, 420, 422-423 (D. Conn. 1972), while others loosely treat the phrase as synonymous with "clearly erroneous." *Duke City Lumber Co.* v. *Butz*, 382 F.Supp. 362, 374 (D.D.C. 1974) ("whether the agency's threshold decision was arbitrary, capricious or otherwise clearly erroneous"); *Daly* v. *Volpe*, 350 F.Supp. 252, 255 (W.D. Wash. 1972) ("it was not clearly erroneous, and therefore it was not arbitrary and capricious").

Post-*Overton Park* decisions, as well as the internal evidence in *Overton Park* itself, *see supra*, have made clear that the Court does not intend the "clear error of judgment" phrase to sanction review more intrusive than traditional "arbitrary and capricious" review; rather, the Court has reaffirmed that the reviewing court must defer if the agency has a rational basis for its decision. *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, *supra* note 73, 419 U.S. at 290; *United States* v. *Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 749 (1972). *See* note 79 *infra*. Thus it

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416. This is particularly true in highly technical cases such as this one.

> A court does not depart from its proper function when it undertakes a study of the record, hopefully perceptive, even as to evidence on technical and specialized matters, for this enables the court to penetrate to the underlying decisions of the agency, to satisfy itself that the agency has exercised a reasoned discretion, with reasons that do not deviate from or ignore the ascertainable legislative intent.

Greater Boston Television Corp. v. *FCC*, 143 U.S.App. D.C. 383, 392, 444 F.2d 841, 850 (1970), *cert. denied*, 403 U.S. 923 (1971). *See also Essex Chemical Corp.* v. *Ruckelshaus*, 158 U.S.App.D.C. 360, 367, 486 F.2d 427, 434 (1973), *cert. denied*, 416 U.S. 969 (1974); *Portland Cement Assn* v. *Ruckelshaus*, 158 U.S.App. D.C. 308, 335, 486 F.2d 375, 402 (1973), *cert. denied*, 417 U.S. 921 (1974); *International Harvester Co.* v. *Ruckelshaus*, 155 U.S.App.D.C. 411, 444, 478 F.2d 615, 648 (1971).[75]

There is no inconsistency between the deferential standard of review and the requirement that the review-

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is important that courts not think themselves licensed to embark upon wide-ranging searches for "clear errors of judgment." Such searches can only distort the established appellate role in reviewing informal agency action. Rather, we think *Overton Park*'s troublesome phrase is best read as no more than an affirmation of the traditional standard of review. Accordingly, in the context of "arbitrary and capricious" review, we shall reverse for a "clear error of judgment" only if the error is so clear as to deprive the agency's decision of a rational basis.

[75] While *Greater Boston Television Corp.* v. *FCC*, 143 U.S. App.D.C. 383, 392, 444 F.2d 841, 850 (1970), *cert. denied*, 403 U.S. 923 (1971), was a substantial evidence case, its statement of the proper scope of a reviewing court's inquiry into the evidence has been adopted by the informal rulemaking cases cited above.

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ing court involve itself in even the most complex evidentiary matters; rather, the two indicia of arbitrary and capricious review stand in careful balance. The close scrutiny of the evidence is intended to educate the court. It must understand enough about the problem confronting the agency to comprehend the meaning of the evidence relied upon and the evidence discarded; the questions addressed by the agency and those bypassed; the choices open to the agency and those made. The more technical the case, the more intensive must be the court's effort to understand the evidence, for without an appropriate understanding of the case before it the court cannot properly perform its appellate function. But that function must be performed with conscientious awareness of its limited nature. The enforced education into the intricacies of the problem before the agency is not designed to enable the court to become a super-agency that can supplant the agency's expert decision maker. To the contrary, the court must give due deference to the agency's ability to rely on its own developed expertise. *Market Street Railway* v. *Railroad Commission*, 324 U.S. 548, 559-561 (1945). The immersion in the evidence is designed *solely* to enable the court to determine whether the agency decision was rational and based on consideration of the relevant factors. *Citizens to Preserve Overton Park* v. *Volpe*, *supra*, 401 U.S. at 416; *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, *supra*, 419 U.S. at 285, 290. It is settled that we must affirm decisions with which we disagree so long as this test is met.[76] *Bowman Trans-*

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[76] This rule has been most directly stated in cases involving substantial evidence review, *see, e.g., Consolo* v. *Federal Maritime Commission*, 383 U.S. 607, 620 (1966); *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 488 (1951); *Environmental Defense Fund, Inc.* v. *EPA* (Coahoma), *supra* note 28, 160 U.S.App.D.C. at 130, 489 F.2d at 1254, but it is nonetheless applicable here as well. The requirement of affirm-

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portation, Inc. v. *Arkansas-Best Freight System, Inc., supra*, 419 U.S. at 290; *United States* v. *Allegheny-Ludlum Steel Corp., supra*, 406 U.S. at 749.

Thus, after our careful study of the record, we must take a step back from the agency decision. We must look at the decision not as the chemist, biologist or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.[77] "Although [our] inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one." *Citizens to Preserve Overton Park* v. *Volpe, supra*, 401 U.S. at

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ing decisions with which we disagree is inherent in *Overton Park*'s command that "[t]he court is not empowered to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park* v. *Volpe, supra* note 69, 401 U.S. at 416.

[77] In a substantial evidence case Judge Wilkey has well delineated our limited role:

> In the case at bar our task is made somewhat simpler than the agency's by adhering conscientiously to the proper scope of judicial review of administrative action, *i.e.*, we as a court are confronted with a problem in administrative law, not in chemistry, biology, medicine, or ecology. It is the administrative agency which has been called upon to hear and evaluate testimony in all scientific fields relevant to its ultimate question of permission or prohibition of the sale and use of DDT. The EPA Administrator had an opportunity to make a careful study of the record of seven months of public hearings and the summaries of evidence prepared for him, heard oral argument, and now has arrived at a decision to ban most uses of DDT. It is *his* decision which we must review; we are not to make the same decision ourselves.

Environmental Defense Fund, Inc. v. *EPA* (Coahoma), *supra* note 28, 160 U.S.App.D.C. at 128, 489 F.2d at 1252 (emphasis in original). *See also* note 53 *supra*.

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416. We must affirm unless the agency decision is arbitrary or capricious.[78]

With the "arbitrary and capricious" standard firmly in mind, we now turn to the evidence supporting the regulations before us.

B. *Overview of the Evidence*

Petitioners vigorously attack both the sufficiency and the validity of the many scientific studies relied upon by the Administrator, while advancing for consideration various studies allegedly supportive of their position. The record in this case is massive—over 10,000 pages. Not surprisingly, evidence may be isolated that supports virtually any inference one might care to draw. Thus we might well have sustained a determination by the Administrator *not* to regulate lead additives on health grounds. That does not mean, however, that we cannot sustain his determination to so regulate. As we have indicated above, we need not decide whether his decision is supported by the preponderance of the evidence, nor, for that matter, whether it is supported by substantial evidence.[79] To the contrary, we must sustain

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[78] In stating the scope of review of informal rule-making by the Interstate Commerce Commission, the Supreme Court succinctly summarized these principles:

> We do not weigh the evidence introduced before the Commission; we do not inquire into the wisdom of the regulations that the Commission promulgates, and we inquire into the soundness of the reasoning by which the Commission reaches its conclusions only to ascertain that the latter are rationally supported.

United States v. *Allegheny-Ludlum Steel Corp.*, *supra* note 74, 406 U.S. at 749.

[79] Review for substantial evidence is mandated only for agency adjudications and formal rule-making proceedings. 5 U.S.C. § 706(2)(E). Since "arbitrary and capricious" re-

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if it has a rational basis in the evidence. Keeping in mind the precautionary "will endanger" standard under which the Administrator acted, we have no difficulty in terming his decision rational.

A word about our approach to the evidence may be in order. Contrary to the apparent suggestion of some of the petitioners, we need not seek a single dispositive study that fully supports the Administrator's determination. Science does not work that way; nor, for that matter, does adjudicatory fact-finding. Rather, the Administrator's decision may be fully supportable if it is based, as it is, on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is cumulative: the more supporting, albeit inconclusive, evidence available, the more likely the accuracy of the conclusion.[80] If, as petitioners suggest, one single

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view does not involve determining whether the agency decision is supported by substantial evidence, it is considered the more lenient form of review. Nonetheless, some have noted that in reviewing the evidence relied upon in agency proceedings, the two standards often seem to merge. *Associated Industries of New York State, Inc.* v. *U.S. Department of Labor*, 487 F.2d 342, 349-350 (2d Cir. 1973) (Friendly, J.). The primary difference between the two in such cases would seem to be that "substantial evidence" review is limited to evidence developed in formal hearings, while "arbitrary and capricious" review of an agency engaged in informal rulemaking is not so limited, but rather may consider the agency's developed expertise and any evidence referenced by the agency or otherwise placed in the record. *Market St. Ry.* v. *Railroad Comm'n*, 324 U.S. 548, 559-561 (1945); *City of Chicago* v. *FPC*, 147 U.S.App.D.C. 312, 322-326, 458 F.2d 731, 741-745 (1971), *cert. denied*, 405 U.S. 1074 (1972).

[80] As Chief Justice Shaw observed over a century ago, "inferences drawn from independent sources, different from each other, but tending to the same conclusion, not only support each other, but do so with an increased weight." *Commonwealth* v. *Webster*, 59 Mass. (5 Cush.) 295, 317 (1850).

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study or bit of evidence were sufficient independently to mandate a conclusion, there would, of course, be no need for any other studies. Only rarely, however, is such limited study sufficient. Thus, after considering the inferences that can be drawn from the studies supporting the Administrator, and those opposing him, we must decide whether the cumulative effect of all this evidence, and not the effect of any single bit of it, presents a rational basis for the low-lead regulations.

While we have studied the record with great care, we do not discuss it all here; to do so would make this already lengthy opinion completely unwieldy. Instead, we shall briefly review the bases for the Administrator's conclusions that petitioners have singled out for special attack.[81] Before we turn to those issues, however, we should note that some things appear to be uncontested. Thus petitioners seem to concede the following: that lead serves no known purpose in the human body; that lead in sufficiently high quantity is destructive to the body, causing anemia, severe intestinal cramps, paralysis, neurologic damage, and, in sufficient dosage, death. Third Health Document at III-1, 2, JA 54-55; that more than 250,000 tons of lead per year are used in production of lead additives, accounting, according to EPA, for approximately 90 percent of all airborne lead,[82] *id.* at Table II-1, JA 46; that lead concentrations in the air over our largest cities are 2,000 times greater than lead concentrations in the air over the mid-Pacific, NAS Report at 205; that lead in the ambient air contributes to body blood lead levels, Nalco Supp. Br. at 37; supplemental brief of petitioners PPG Industries and E.I.

[81] Both petitioners and the Wilkey dissent (hereinafter dissent) engage in a detailed attack on the evidentiary basis for the Administrator's decision. Their arguments are considered in corresponding detail in the appendices to this opinion.

[82] *See* note 60 *supra.*

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duPont de Nemours & Company (hereinafter PPG/duPont Supp. Br.) at 23; and that blood lead levels are a reasonable indication of the body's lead burden. Stripped of their generalized and largely unsubstantiated claims of "bias" and "distortion of the evidence," petitioners principally challenge three EPA conclusions: (1) that, based on a preliminary determination that blood lead levels of 40 ug are indicative of danger to health, elevated blood lead levels "exist to a small but significant extent in the general adult population, and to a very great extent among children," Third Health Document at VII-3, JA at 144; (2) that airborne lead is directly absorbed in the body through respiration to a degree that constitutes a significant risk to public health; and (3) that airborne lead falls to the ground where it mixes with dust and poses a significant risk to the health of urban children.

1. *Blood Lead Levels are Elevated Among the General Public*

a. *Blood lead levels of 40 ug are indicative of danger to health.* Although recognizing that a blood lead level of 40 ug "does not represent a sharp demarcation between health and disease," the Administrator found it "prudent to regard blood lead levels over 40 ug/100 g as indicators of lead intake that should be prevented." Third Health Document at III-11, JA 64. Petitioners contest this determination. Much of their argument, however, adds up to nothing more than that they are unhappy the Administrator chose to exercise his judgment and think the statute does not permit such discretion. Petitioners cite medical studies that show not that a blood lead level of 40 ug is unrelated to danger, but that scientists are simply uncertain about the effect of such blood levels. Ethyl brief at 37-38 and Supp. Br. at 41-42; PPG/duPont brief at 11-12; Nalco brief

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at 14. But, as we have seen, exercise of reasoned discretion based on the evidence is not only permitted, but mandated, by Section 211(c)(1)(A). The Administrator recognized from the outset that the health effects of varying human blood lead levels were uncertain and that continuing research was necessary.[83] His determination of the 40 ug level is, on its face, an assessment of risks based on the known facts and not improper as such.

In addition to their generalized attack on the Administrator's power, petitioners challenge the sufficiency of the evidence to support his determination. Under the "will endanger" standard, however, we find the evidentiary basis for the Administrator's determination to be more than adequate. Petitioners do not contest the recommendation of the United States Public Health Service that 80 ug be taken as the standard of unequivocal lead poisoning, or the Service's recommendation that blood lead levels of 50-79 ug justify immediate evaluation for possible lead poisoning. Medical Aspects of Childhood Lead Poisoning, HSMHA Health Reports, 86 (2), 140-143 (1971), *cited in* Third Health Document at IV-3, JA 71. What draws petitioners' fire is only

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[83] Indeed, at the conclusion of Section IV of the Third Health Document, "Can an Acceptable Lead Body Burden be Defined?," the Agency suggested seven important areas for future inquiry. Third Health Document at IV-7, 8, JA 75-76. Ethyl claims these questions only demonstrate "that EPA is unable at this time to support its blood lead level theories with pertinent data * * *." Ethyl brief at 38. To the contrary, the questions only show the candor with which the Agency has approached this important issue. Sufficient data exists for the Administrator to assess risks and make a judgment within the "will endanger" standard. That further data would enable the Agency to deal more precisely with the problem does not undercut the Administrator's judgment. It is the nature of scientific inquiry that further data will always permit such refinement.

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the last of the Service's recommendations, adopted by EPA, that for older children and adults "a blood lead concentration of 40 ug or more per 100 ml of whole blood * * * be considered evidence suggestive of undue absorption of lead, either past or present." *Id.* While the reasonableness of establishing as a danger point a lead exposure level somewhat lower than that at which actual damage may occur seems both logically unassailable and well within the intent of the "will endanger" standard, the Administrator went beyond that sufficient conclusion. He recognized, and warned of, possible dangers, particularly to children, from lead at the 40-60 ug level, and even below, thereby suggesting that the Public Health Service's recommended danger level, designed for adults, may be set too high. Because this latter evidence was only suggestive, however, the Administrator conservatively settled on the 40 ug standard.[84] Third Health Document III-5, 6, 7, 8, JA 58-61. Such a "prudent" determination is well within the Administrator's discretion under the "will endanger" standard. We have examined the evidence relied upon carefully and, while it is not necessary to summarize it here,[85] we find that

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[84] Petitioners Ethyl and Nalco specially attack the Administrator's reliance on these subclinical effects of exposure to low lead levels both here and in assessing the damages from dustfall. Ethyl Supp. Br. at 45; Nalco Supp. Br. at 30-34. In fact, however, petitioners merely repeat the very qualifications on the evidence that led the Administrator to discount its value. Petitioners and the Administrator agree far more than they disagree on this issue. We cannot say it was irrational for the Administrator to note the possibility of subclinical effects, nor can we say it was irrational for him largely to discount their probability. Accordingly, we must reject petitioners' argument.

[85] A few examples indicate the kind of evidence before the Administrator:

[continued]

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it provides a rational basis for the Administrator's determination.

b. *Blood lead levels are elevated among a small, but significant, number of adults and a considerable number of children.* Again, petitioners challenge the Administrator's determination as unsupported by the evidence. The problem here is one of choosing among the items of evidence. Petitioners rely heavily on the results of the so-called Seven Cities Study,[86] which found a very small percentage of adults with elevated (in excess of 40 ug) blood levels.[87] PPG/duPont brief at 12-15; Nalco brief at 16. The Administrator, on the other hand, finds serious methodological flaws in the Seven Cities Study

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A study by David *et al.* associating increased frequency of hyperactivity among children with blood lead levels of 25-55 ug. *Cited in* Third Health Document at III-6, 7, JA 59-60.

A study by Piomelli *et al.* which found that 55% of children tested with blood lead levels of 40-59 ug and 100% of those tested with blood lead levels in excess of 60 ug had demonstrable evidence of metabolic interference with heme synthesis in the bone marrow. *Cited in* Third Health Document at IV-3, 4, 5, JA 71-73.

A study by Tola *et al.* finding mild anemia in lead workers with blood lead levels in the 40-60 ug range. *Cited in* Third Health Document at III-6, JA 59.

A study by Pueschel *et al.* suggesting that in children lead body burdens below those usually associated with clinical lead poisoning may contribute to renal as well as neurological damage. *Cited in* Third Health Document at III-5, JA 58.

[86] Tepper & Levin, "A Survey of Air and Population Lead Levels in Selected American Communities," Dept. of Environmental Health, College of Medicine, U. Cincinnati, Ohio (EPA Contract PN 22-68-28) (Dec. 1972), JA 840 (hereinafter Seven Cities Study).

[87] Ethyl also once again attacks the mere fact that the Administrator exercised his judgment. *See* Ethyl brief at 47.

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that limit its usefulness, 38 FED. REG. 33735, and relies instead on studies which concededly support his conclusion, Third Health Document at Tables VII-1, 2 & 3, JA 145-147, but which petitioners score as representative only of certain occupational groups. PPG/duPont brief at 15; Nalco brief at 15-16.

Having analyzed this evidence and the arguments of the parties, we would again defer to the Administrator's judgment. First we note that, while contesting the source of lead exposure, petitioners do not challenge at all the Agency's conclusion that blood lead levels are elevated in a large number of children, including a possible 25 percent of all preschool children living in substandard housing.[88] Third Health Document at Table VII-3, JA 147.

Next, while the studies relied on by the Administrator are largely of various occupational groups, they are

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[88] Petitioners PPG Industries, Inc. (PPG) and E. I. duPont de Nemours & Company (duPont) charge that this conclusion has no bearing on whether there is undue lead exposure among the general adult population. PPG/duPont Supp. Br. at 19. Of course it does not. It does have bearing, however, on whether blood lead levels are elevated among children and among the general population, both adult and child. It is for this purpose that the conclusion is cited.

Ethyl argues that these children have high blood lead levels primarily because of exposure to lead-based paint. Ethyl Supp. Br. at 40-41. The Administrator does not disagree. 38 FED. REG. 33735. What is important for his purpose is that blood lead levels are elevated in the general public; under the cumulative impact theory the source of the elevation is irrelevant in determining whether the public health is endangered by exposure to lead. *See* pages 56-61 *supra*. The source becomes relevant only when deciding whether the emission products of lead additives make a significant contribution to that exposure, thereby justifying regulation under § 211(c)(1)(A).

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frequently occupations whose only exposure to lead is through the ambient air in which their workers—policemen, mailmen, service station employees, parking lot attendants, and the like—are forced to spend their working hours.[89] Third Health Document at Table VII-1, JA 145. Contrary to the arguments of petitioners, studies of occupational groups are often particularly valuable in acting as an early warning system of possible effects on the public at large. The intensive exposure in particular occupations essentially accelerates the effects of long-term exposure of the general public and provides an identifiable, highly exposed, and readily accessible

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[89] NPRA, PPG and duPont suggest that if certain occupational groups are overexposed to lead concentrations in the air, they should be protected under the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.*, rather than the Clean Air Act. NPRA Supp. Br. at 6-8; PPG/duPont Supp. Br. at 20. Other than by issuing mailmen, policemen, and service station attendants gas masks, we are baffled as to how special occupational regulations could protect such overexposed groups, who are overexposed only because they must work outdoors on or near busy city streets. We have no doubt, however, that the Clean Air Act was intended to protect such people. As Sen. Muskie stated "for the purposes of the record":

> In setting standards, not only ambient standards but emission standards, * * * we must be concerned with the health effect upon the most vulnerable in our population * * *.

Hearings on S. 3229, S. 3455, S. 3546 before the Subcomm. on Air and Water Pollution of the Senate Comm. on Public Works, 91st Cong., 2d Sess. at 74 (1970). No less than with "particularly sensitive citizens such as bronchial asthmatics and emphysematics" who receive the special attention of the Clean Air Act, S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970), citizens who are occupationally exposed outdoors to otherwise uncontrollable lead concentrations in the ambient air are among "the most vulnerable in our population" and deserve to be considered when regulations under § 211(c)(1)(A) are at issue.

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group of research subjects. *See* D. CLARK & B. MACMAHON, PREVENTIVE MEDICINE 26 (1967) (hereinafter CLARK & MACMAHON). Thus much of the evidence in *Reserve Mining* of the danger to the general public of absorption of asbestos particles came from epidemiological studies of asbestos workers. *Reserve Mining Co. v. EPA*, *supra*, 514 F.2d at 507.[90] Because of this the occupational data are not only in themselves indicative of high blood lead levels among a significant portion of the adult population, but they suggest the future likelihood, absent controls, of increasing high blood lead levels among even more widely dispersed portions of the public. In any case, however, the evidence relied upon by the Administrator was not only of occupational groups. Some evidence of high blood lead level relates to such "specialized" groups as "Drivers of Cars," "Male Commuters," and "Urban" residents. Third Health Document at Tables VII-1 & 2, JA 145-146.

Petitioners argue that the negative conclusions of the Seven Cities Study and several other studies should

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[90] The dissent criticizes this comparison of the Administrator's use of studies of occupational groups with the Eighth Circuit's use of similar evidence on the ground that the court explained the validity of its use of occupational data whereas the Administrator did not. Dissent at 73. The Administrator, however, based his inferences on studies of occupational groups whose lead intake results from exposure, albeit for longer than average periods of time, to the same air breathed by the general public. *See* pp. 81-82 *supra*. The Eighth Circuit, by contrast, was explaining the validity of inferring a hazard to the general public from studies showing a hazard to workers and others exposed to higher levels of a somewhat different substance than that with which the court was concerned. *See* 514 F.2d at 511-512. In short, the Eighth Circuit was faced with a situation where differences between the hazard facing the occupationally exposed group and the hazard facing the general public required that the propriety of reaching a conclusion about the public from occupational studies be explained; the Administrator was not.

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outweigh the positive indications of the studies described above. PPG/duPont Supp. Br. at 16-23; NPRA Supp. Br. at 5-8. The Administrator disagreed, and we cannot fault his conclusion. Because of the many uncontrolled variables in epidemiological studies, valid conclusions may be obscured. But, while the possibility of false negative conclusions is a real one, the possibility of false positive findings is considerably less likely. CLARK & MACMAHON, *supra*, at 100. Thus the Administrator credited the occupational and other studies reporting a small, but significant, portion of the general population with elevated blood lead levels and discounted the negative studies on which petitioners rely. Third Health Document at VII-3, JA 144. We cannot say his conclusion was arbitrary or capricious.

2. *Automobile Lead Emission Products Are Directly Absorbed in the Body to a Significant Extent*

Since it is apparent from the face of his decision and the Third Health Document that the Administrator considered all the evidence before him, the only issue is whether he treated that evidence in a rational manner. Petitioners have now conceded that lead emissions are directly absorbed in the body from the ambient air, and they challenge only whether the extent of absorption is significant enough to justify these regulations. Nalco Supp. Br. at 37; PPG/duPont Supp. Br. at 23. The Administrator's conclusion that lead absorption from the air is significant is amply supported by the record in this rule-making.

The Administrator relied on three types of evidence: theoretical, epidemiological, and clinical studies. The theoretical evidence consisted of a set of calculations designed to estimate the amount of lead in the air which, when added to an average dietary intake, would suffice to bring the blood lead burden of a "standard man" up

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to 40 ug.[91] These calculations indicated that the 40 ug level can be reached by exposure to ambient air lead concentrations no greater than those now found in parts of our larger cities. Significantly, the results of two clinical experiments support the estimates derived from these theoretical calculations. The calculations, as well as petitioners' misguided attacks on their validity, are discussed in Appendix A to this opinion. *See* pages A-1 to A-4 *infra*.

The second type of evidence relied upon by the Administrator in reaching his conclusion that airborne lead contributes significantly to the human lead body burden consisted of epidemiological research. Epidemiologists study the effects of various phenomena on humans under uncontrolled or "natural" conditions. These effects are correlated with other observed facts in an attempt to develop significant relationships among the data. The science is limited, however, in that inferences may be drawn, but relationships cannot be proved by the correlations alone. JA 583. The studies before the Administrator were of large groups of people; correlations were sought between blood lead level and exposure to lead in the ambient air. The studies were confounded, however, by the multiple sources of lead. Since diet accounts for a major portion of the body lead burden, an individual's blood lead level varies not only according to his exposure to lead in the ambient air, but according to his daily dietary intake of lead. Wide variations in dietary lead intake, which are common, can completely mask the effects of air lead absorption. Nonetheless, none of the epidemiological studies could control or measure dietary lead intake. This uncertainty in the data severely limited the usefulness of the broadly con-

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[91] EPA specifically requested comment on the figures it used in calculating the respiratory absorption of lead by a "standard man." 37 FED. REG. 11787 (1972), JA 21.

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ceived epidemiological studies and led the Administrator to rely instead on data limited to situations in which dietary exposure could roughly be termed constant.

Following this rationale, the Administrator focused on the consistent relationship found between air and blood lead levels within particular metropolitan areas, rather than on the lack of such a relationship between areas.[92] *See* pages A-5 to A-9 *infra*. The Administrator

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[92] The dissent suggests that this court, not the Administrator, first propounded this rationale for relying on the intrametropolitan results of the epidemiological studies. Dissent at 76-77. This critique ignores the facts that the Administrator referred to this explanation at the beginning of his opinion, JA 3, and that the Third Health Document identifies the language in the Seven Cities Study which justifies the Administrator's reliance on that study's intrametropolitan area data. JA 89, *quoting* JA 844 (the introductory summary of the Seven Cities Study). The section of the Seven Cities Study summarized by the language quoted in the Third Health Document explicitly states the rationale relied on by the Administrator. JA 892; *see* pp. A-5 to A-6 & note 4 *infra*. Clearly, the "agency's path" to its decision to credit the intrametropolitan results "may reasonably be discerned." *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, *supra* note 73, 419 U.S. at 286.

Despite its origins in the Seven Cities Study itself, the dissent rejects this explanation for the Administrator's approach to the evidence as totally irrational. The dissent argues that it is illogical to maintain that intrametropolitan dietary lead can be assumed to be relatively constant despite the income differences in a large metropolitan area. This argument, which has no foundation in any material before this court, illustrates the danger of "plausible-sounding, but simplistic, judgments of the relative weight to be afforded various pieces of technical data." Concurring op. of Chief Judge Bazelon at 2. Without ourselves attempting to assume a scientific role, we note that since the main source of dietary lead is the soil, *see* note 5 *supra*, the geographical origin of foodstuffs may be a more important determinant of their lead content than is price. In any event, whatever the underlying

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also drew support for his conclusion that lead in the air significantly affects lead in the blood from studies conducted in single neighborhoods. There, too, confounding factors were minimized by proximity, and there, too, a clear direct relationship was found. *See* pages A-11 to A-14 *infra*. Thus the epidemiological studies, although perhaps insufficient to justify the Administrator's decision if considered singly or even collectively, were reasonably relied on as part of the basis for the low-lead rules.

The conclusions the Administrator drew from theoretical calculations and the epidemiological studies are significantly bolstered by two important clinical studies. Clinical studies are laboratory experiments on humans in which variables can be controlled and causal relationships demonstrated. Clinicians attempt to reproduce atmospheric conditions in the laboratory and measure the response to pollution of small numbers of humans chosen to represent the population at large. JA 583. Because of its necessarily significant intrusion on the subjects' lives, clinical research is limited in the number of subjects it can study. Nonetheless, the two clinical studies are especially valuable since they are the only attempts to control or account for dietary lead intake. Thus they sought to measure the contribution of respiratory absorption of lead unmasked by variations in dietary lead. Both studies found that airborne lead provided a significant portion of the lead in the blood of the experiments' subjects. Moreover, the amount of lead actually absorbed from the air during these studies corresponded closely with the amount EPA's theoretical calculations predicted would be absorbed. *See* pages A-14 to A-18 *infra*.

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basis for this approach might be, the important point is that we have no reason to fault the Administrator's decision to rely on the scientific expertise of the authors of the epidemiological studies before him.

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While we must consider petitioners' arguments carefully, the necessary existence of limitations and inconsistencies in the data remind us to observe carefully our limited appellate function. It does not matter whether or not we agree with the Administrator's determination. Nor does it matter whether the evidence might support a conclusion contrary to that reached by the Administrator. All that is of concern to us is that there be a rational basis in the evidence for the conclusion reached. We cannot say there is not. The bulk of the evidence cited supports the Administrator. *See* Appendix A to this opinion. The Administrator treated *all* the evidence in a consistent and rational manner. This treatment disposed of most of the studies relied upon by petitioners, leaving the plain conclusion that lead emissions form a significant part of the human body burden. Particularly in light of the precautionary nature of the "will endanger" standard, we cannot find the Administrator's conclusion to be arbitrary or capricious. Accordingly, we must uphold his determination.

3. *Lead Exposure from Dustfall Threatens the Health of Children*

While we would have no difficulty in sustaining the low-lead regulations solely on the basis of the evidence and conclusions discussed above, the Administrator based his decision to regulate on other evidence as well. He presented a hypothesis, which he found consistent with known information, that urban children are particularly threatened by lead additives in that they are prone to ingest lead emissions that have fallen to the ground and mixed with dust. While the hyopthesis is admittedly not proved as fact, we need not decide whether it would be sufficient by itself to support the low-lead regulations, for it is offered only in support of the evidence already presented. Petitioners vigorously attack the hypothesis nonetheless, but constantly confuse the issue by ignoring

the flexibility of the "will endanger" standard and by attempting to refute the Administrator with evidence that he both understands and has accounted for. Thus it is helpful first to set these matters straight.

First, as we have demonstrated above, *see* pages 17-36 *supra*, the "will endanger" standard is a precautionary standard that embraces a wide range of permissible proof. It is therefore no objection to the dustfall hypothesis that it is merely a hypothesis. A supportable and reasonable hypothesis may well form the basis for regulations under Section 211(c)(1)(A). Indeed, the totality of evidence relied upon in the *Reserve Mining* case constituted no more than such a hypothesis. *See* pages 93-94 *infra*.

Second, although it seems too obvious to mention, the Administrator understood and expressly recognized that leaded paint "is the primary cause of clinical lead poisoning" in children, 38 FED. REG. 33735. Although petitioners repeatedly try to rebut EPA conclusions by stating this fact, the Administrator was well aware of it and his evaluation of the data before him invariably accounted for it. We do not believe the importance of lead paint to the lead poisoning problem in children invalidates the Administrator's reliance on the dustfall theory. The Administrator justified his hypothesis as a basis for regulation on grounds that dustfall may be regulated far more readily than leaded paint, that dustfall contributes significantly to the threat from leaded paint by raising blood lead levels so as to make lead poisoning easier to contract, and that even when acute lead poisoning does not develop absorption of lead dustfall may cause undesirable and avoidable subclinical effects. 38 FED. REG. 33736-33737.[93] We have held, *see*

[93] Petitioners' persistent refusal to recognize that these are the reasons the Administrator is concerned about lead dustfall makes their constant arguments about leaded paints com-

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pages 56-61 *supra*, that concern about the cumulative impact of exposure to various lead sources may justify regulation of lead additives under Section 211(c)(1)(A). Thus we cannot say that these reasons for regulation, when added to the demonstrated danger to the general public from respiratory absorption of lead emissions, *see* Appendix A to this opinion, and if supported by the evidence, do not form a permissible basis for the low-lead regulations under the "will endanger" standard.

With these preliminaries settled, we turn to the evidence supporting the Administrator's determination. Since the hypothesis is only a secondary basis for the regulations, and since the evidence cited goes considerably beyond that necessary to establish the hypothesis as reasonable, we shall address only the thrust of petitioners' objections and the Administrator's responses. The logical steps to the Administrator's conclusion are these:

> a. High lead concentrations in dust and dirt are prevalent in urban areas.
>
> b. In most circumstances, lead from exhausts and not lead paint or lead from stationary sources is the primary source of lead in urban dust and dirt.
>
> c. Children prone to pica, about 50 percent of those between the ages of one and three, eat non-food objects, including dust and dirt.
>
> d. As a result of ingesting dust and dirt contaminated with lead fallout, children can be expected to absorb lead into their bodies.

38 FED. REG. 33736. If the intermediate steps are supported by the evidence, the validity of the Administrator's conclusion as a reasonable hypothesis is unassailable. Our study of the underlying evidence con-

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pletely unresponsive to the Administrator's analysis of the evidence.

vinces us that it is firm and convincing, and certainly sufficient to support the Administrator's hypothesis as reasonable.

Petitioners concede that lead concentrations are high in the dust near highways and adjacent to homes with lead paint. They contest, however, that high lead concentrations are otherwise prevalent in urban areas. PPG/duPont Supp. Br. at 37 n.86. The facts rebut their argument. The NAS Panel found that "[t]he concentration of lead in street dust and surface soil of large cities is *extremely* high." NAS Report at 30 (emphasis added). This conclusion was based on a finding that, compared to the usual range of dust lead concentrations of 2-200 parts per million (ppm), dust lead concentrations in cities averaged 1,636 ppm and 2,413 ppm respectively for residential and commercial sites. Even in city parks lead concentrations ranged from 194 ppm to 3,357 ppm. *Id.* Other evidence of record shows high lead concentrations in Central Park Zoo in New York City, JA 2630, and school playgrounds in Philadelphia, JA 674.

Where does this high dust lead content come from? The Administrator concluded that since 90 percent of the lead in the ambient air is from automotive exhausts and since, as petitioners concede, PPG/duPont Reply Br. at 17, the lead eventually settles to the ground, most of the lead in dust is a product of automobile lead emissions. Petitioners do not seriously contest this; indeed their own studies suggest this by showing that lead content in soil decreases with distance from highways.[94] Rather, they argue that "lead from paint or stationary sources is the source of lead in dust and dirt in areas where young children play." PPG/duPont Supp. Br. at 37 n.86.

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[94] Ter Haar & Aronow, New Information on Lead in Dirt and Dust as Related to the Childhood Lead Problem, presented at the EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N.C., Oct. 1, 1973, JA 917, 922 (Fig. 1).

This argument reflects petitioners' consistent refusal to recognize that city children play regularly in city streets, where petitioners concede lead dustfall from automobiles accumulates. PPG/duPont Reply Br. at 17. Since the Administrator's concern about dustfall is based on the harm it may cause city children, petitioners' argument that children are not exposed to automobile dustfall where they play must be rejected.

Petitioners do not contest that pica is a common phenomenon among preschool children, although they note that it "is a psychological disorder; it is not characteristic of all children * * *." PPG/duPont Supp. Br. at 37 n.86. While this is certainly true, pica is characteristic of a significant number of children. Petitioners do not challenge the conclusion of the NAS Panel that pica occurs in at least 50 percent of both middle- and lower-class children. NAS Report at 133.

On the basis of this evidence alone it is reasonable to hypothesize that children with pica will ingest dust and dirt containing lead dustfall from automobiles. Indeed, on such limited evidence the NAS Panel accepted the dustfall hypothesis as credible:

> Airborne lead wastes from such sources as automobile emissions and the weathering and demolition of old buildings can be expected to have a significant additive effect on the total intake. This would be sufficient to evoke compensatory metabolic responses that are now considered subclinical (such as increased urinary ALA), at the very least. *It may be estimated that dustfall from airborne lead, if swallowed, can make a significant contribution to a small child's total lead intake and thereby contribute to the occurrence of lead poisoning, especially in urban areas.* Even so, the direct ingestion of lead-pigment paints is clearly the principal environmental source in cases of severe acute lead poisoning in young children.

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NAS Report at 140 (emphasis added). Again petitioners focus on the last sentence and emphasize the danger from leaded paints. Since the Administrator is in agreement with them on the point, however, their arguments are superfluous.

Petitioners' primary claims are not addressed to the evidence that establishes the dustfall hypothesis as tenable. Rather, they argue that there is no evidence that lead dustfall from automobiles is in fact swallowed by children with pica. While such proof is not necessary to establish the Administrator's hypothesis as reasonable, *see* pages 90-91 *supra*, we note that a considerable amount of circumstantial evidence does support his conclusion. *See* Appendix B to this opinion.

In any case, all the evidence suggesting that the children with pica tend to eat dust contaminated with lead fallout from automobiles takes the Administrator's theory far beyond the hypothesis stage. He offered only a tentative result, "a hypothesis consistent with information provided by a variety of studies." 38 FED. REG. 33736. Undoubtedly, he has shown that. Indeed, as reasonable medical hypotheses go, this one is particularly solid. This is vividly demonstrated by recalling the kind of evidence relied upon to justify similar precautionary relief in *Reserve Mining*.

The question in that case was the validity of the hypothesis that *ingestion* of asbestos fibers was dangerous to health. The reason for concern was that epidemiological studies had associated *inhalation* of asbestos with cancer. The evidence supporting the hypothesis was of three kinds: (1) a court-sponsored study to determine whether asbestos fibers were present in residents who drank the polluted water; (2) animal studies designed to measure whether asbestos fibers can be absorbed into the body from the stomach; and (3) epidemiological studies associating inhalation of asbestos fibers with gastrointestinal cancer and the theory that this may be due

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to ingestion of asbestos fibers initially inhaled. *Reserve Mining Co.* v. *EPA*, *supra*, 514 F.2d at 514. Upon review of the evidence the court concluded (1) asbestos fibers were *not* present in long-time residents; (2) the animal studies were *ambiguous* on whether asbestos fibers could be absorbed if ingested; and (3) the theory that asbestos workers ingested asbestos fibers as well as inhaled them was no more than a theory, *id.* at 514-516. Nonetheless, solely on the basis of this evidence, the court concluded that "the theory that excess cancers may be attributed to the ingestion of asbestos fibers rests on a tenable medical hypothesis," *id.* at 516. On the basis of this tenable hypothesis, the court accepted the further hypothesis that asbestos could be ingested from the drinking water and that, therefore, there was a "reasonable medical concern" for the public health which justified abatement of the asbestos discharge under the "endangering" language of the FWPCA. *Id.* at 520.

None of these uncertainties cloud the Administrator's dustfall hypothesis. Lead is present in children, and in elevated amounts. Children do ingest dust, and dust is heavily laden with lead. Animal studies prove that ingested lead dust is absorbed into the bloodstream. And epidemiological studies associate high lead concentrations in children with high lead concentrations in dirt and dust, and with proximity to automobiles. Since the automobile is the predominant source of lead in dust, the Administrator's hypothesis stands firm as reasonable, undoubtedly with more support in studies already made than the hypothesis that justified regulation in *Reserve Mining*. Indeed, the primary difference between this case and *Reserve Mining* is that the Eighth Circuit justified ordering abatement of asbestos discharges into the water *solely* on the basis of a hypothesis,[95] while here the hy-

[95] Since proof of the danger posed by inhalation of asbestos wastes was much stronger than proof of the danger posed by

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pothesis is offered only as support for the regulations, the primary basis being the demonstrated danger to health posed by inhalation of lead emissions. In this context, and keeping in mind the precautionary nature of the "will endanger" standard, we have no difficulty in finding the dustfall hypothesis sufficiently well grounded to support the Administrator's limited reliance on it.[96]

C. *Summary of the Evidence*

From a vast mass of evidence the Administrator has concluded that the emission products of lead additives will endanger the public health. He has handled an extraordinarily complicated problem with great care and candor. The evidence did not necessarily always point in one direction and frequently, until EPA authorized research, there was no evidence at all.[97] The Adminis-

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ingestion, the *Reserve Mining* court ordered immediate action taken with regard to the discharge of wastes into the air. *See* note 34 *supra*.

[96] The dissent states that its disagreement with the Administrator and the majority concerning the interpretation of the "will endanger" standard "reduces itself to semantics." Dissent at 4. The dissent also rejects the Administrator's reliance on the dustfall hypothesis simply because it is a hypothesis. Dissent at 84-85. Yet as we have demonstrated above and as the *Reserve Mining* court held, a reasonable hypothesis supported by evidence is a sufficient basis for regulating under the "will endanger" standard as the Administrator has interpreted that standard.

[97] This fact completely rebuts petitioners' claim that this case does not present problems "on the frontiers of scientific knowledge." *Industrial Union Department, AFL-CIO* v. *Hodgson, supra* note 35, 162 U.S.App.D.C. at 338, 499 F.2d at 474. *See, e.g.*, NPRA Supp. Br. at 49. Although petitioners note that lead additives have been in use for over 50 years, and that questions about their safety have been raised for almost as long, *see* note 3 *supra*, the fact remains that virtually all the evidence cited by both EPA and petitioners was de-

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trator reached his conclusion only after hearings spread over several months, consideration of thousands of pages of documents, publication of three health documents, three formal comment periods, and receipt of hundreds of comments. Each study was considered independently; its worth was assessed only after it was measured against any critical comments. From the totality of the evidence the Administrator concluded that regulation under Section 211(c)(1)(A) was warranted.[98]

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veloped in the last five years, most of it for the purpose of supporting or opposing these regulations. *Cf.* note 3 *supra.* Moreover, both EPA and petitioners admit much more remains to be discovered. *See* pp. 48-49 and note 83 *supra.*

[98] The dissent's repeated assertion that the evidence was insufficient to convince the independent scientific community, represented by other Government agencies, is unconvincing for two reasons. First, the Department of Health, Education, and Welfare, which shares with EPA responsibility for and scientific expertise in the areas of public and environmental health, endorsed the regulations. The dissent relies on a Jan. 29, 1973 letter from then Secretary of HEW Elliot Richardson to demonstrate the Department's opposition to the lead reduction regulations. Dissent at 14. The Aug. 7, 1973 letter of Richardson's successor, Caspar Weinberger, in which the Department endorsed removing lead from gasoline provided the result would not be the introduction of more harmful additives, JA 2507, is unconvincingly discounted. Dissent at 13-14 n.27. We have found reasonable the Administrator's determination that reducing the lead content of gasoline would not have this perverse effect on the public health. *See* pp. 64-66 & notes 67-68 *supra.*

Second, the dissent's equation of the views of other Government agencies with the views of the independent scientific community is itself fallacious. Without in the least impugning their motivation, it may be assumed that agencies such as the Department of the Interior and the Department of Commerce, *see* dissent at 9, 14, respond to and represent interests other than those concerned with the environment and the public health. The very existence of EPA is evidence that Congress believed the other agencies of the Government could

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In tracking his path through the evidence we, in our appellate role, have also considered separately each study and the objections petitioners make thereto. In no case have we found the Administrator's use of the evidence to be arbitrary or capricious. Having rejected the individual objections, we also reject the overall claim of error. We find the Administrator's analysis of the evidence and assessment of the risks to be well within the flexibility allowed by the "will endanger" standard. Accordingly, we affirm his determination that lead emissions "present a significant risk of harm to the health of urban populations, particularly to the health of city children." 38 FED. REG. 33734.

IV. EPA PROCEDURES

Petitioners' last major objection to the low-lead regulations is the claim that they are procedurally defective in that, after allowing a total of three formal comment periods, the Administrator did not allow a fourth prior to issuing the regulations.[99] Petitioners claim this de-

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not adequately appraise and act against environmental threats. Truly independent scientific opinion, represented by comments from those with no association with environmental groups or industry, favored the regulations by a margin of approximately two to one. JA 5.

We also note that the California Air Resources Board has recently adopted regulations imposing a more stringent lead reduction schedule than is imposed by the regulations before us. *See* N.Y. Times, Feb. 20, 1976, at 12 col. 3.

[99] Since EPA never stopped accepting comments on the proposed regulations, the comment period on these regulations actually lasted almost two years. All comments were made public when they were received, in accordance with the procedure established by EPA's notices of proposed rule-making. *See, e.g.*, 38 FED. REG. at 1260, JA 17; 17 FED. REG. at 3882, JA 23. Moreover, in keeping with his statutory mandate to consider "*all* relevant medical and scientific evidence available to him," § 211(c)(2)(A), 42 U.S.C. § 1857f-6c(c)(2)(A) (emphasis added), the Administrator considered com-

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prived them of administrative due process in contravention of the demands of Section 4 of the Administrative Procedure Act, 5 U.S.C. § 553 (1970). Ethyl Br. at 50; PPG/duPont Br. at 43; Nalco Br. at 64; NPRA Br. at 44. We find the argument to be without merit.

Section 4 requires that prior to final promulgation of a rule the agency must make public "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). The courts have added useful flesh to this statutory language. The notice should be sufficiently descriptive of the "subjects and issues involved" so that interested parties may offer informed criticism and comments. *See, e.g., Portland Cement Assn* v. *Ruckelshaus*, 158 U.S.App. D.C. 308, 325-327, 486 F.2d 375, 392-394 (1973), *cert denied*, 417 U.S. 921 (1974); *Mobil Oil Corp.* v. *FPC*, 157 U.S.App.D.C. 235, 248 n.39, 483 F.2d 1238, 1251 n.39 (1973). But the notice need not contain "every precise proposal which [the agency] may ultimately adopt

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ments received throughout this extended comment period. *See* pp. 109-110 & note 123 *infra*.

NPRA claims that placing the new studies in the public file did not satisfy EPA's obligations because "EPA did not notify the public of the availability of these documents or that it intended to rely upon them in promulgating the final regulations." NPRA Reply Br. at 17. This statement is not accurate, since EPA's public notice of the proposed low-lead rulemaking, *supra*, stated that all new information received concerning the proposed regulations would be made available for public inspection at its Office of Public Affairs. 38 FED. REG. at 1260, JA 17. Moreover, NPRA's own submissions refer to documents contained in the EPA public file. *See* JA 1962; Doc. 1259. *See also* Doc. 1089 (letter from Ethyl, dated Oct. 12, 1973, requesting that certain documents not yet in the public file be placed there). Since the statute requires the Administrator to consider all evidence available to him, the complaint that petitioners could not know the Administrator would make use of the material in the public file is unimpressive.

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as a rule." *California Citizens Band Assn* v. *United States*, 375 F.2d 43, 48 (9th Cir.), *cert. denied*, 389 U.S. 844 (1967). This last qualification is important since the notice invites comments and the comments will frequently prompt changes in the ultimate regulations.

There is nothing in Section 4 that requires new notice whenever the agency responsibly adopts the suggestions of interested parties. Nonetheless, in this case the Administrator did just that. When, after two comment rounds, criticism of the regulations originally proposed prompted him to alter somewhat the theories on which he was acting, he did not simply promulgate final rules based on these new theories. Rather, he reproposed the regulations as amended and opened them up for a third comment round. It was only when the final regulations were issued that the Administrator omitted a fourth comment period. There was no reason for further comment. The Agency theories underlying the final regulations were identical with those of the Second Health Document and reproposed regulations. The Third Health Document differs from the Second only in that it incorporates new information received since the reproposal and responds to the comments. The only change in the regulations as issued was the switch, supported by comments from a majority of refiners, from leaded pool averaging to total pool averaging.[100]

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[100] The reproposed regulations had made clear that these two alternatives were under consideration and that, at the time, the Administrator favored leaded pool averaging. 38 FED. REG. 1260 (1973). When the majority of industry comments favored use of the total pool system, 38 FED. REG. 33739 (1973), the Administrator shifted his position. While we think the notice at 38 FED. REG. 1260 was a sufficient basis for a change in position in the final regulations, the Administrator gave actual notice of the change to the refiners several months before the final regulations were promulgated. *See* NPRA letter dated Oct. 25, 1973, JA 1962. Moreover, petitioner NPRA submitted comments on that change. *See id.*

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All significant new information developed during the rule-making in this area on the frontiers of scientific knowledge was made available to petitioners and the public for comment well in advance of issuance of the final regulations on November 28, 1973.[101] Thus both the requirements and the spirit of Section 4 were complied with. Nevertheless, the dissent vigorously and at length [102] attacks the Administrator's use of several stud-

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[101] Since all material information was made available for comment by petitioners and the public, it is not necessary for us to determine whether the Administrator may rely on information not previously made available.

[102] By contrast, the division majority allotted less than one and a half pages of its 73-page opinion to this argument. Petitioners also treated this contention as a minor part of their attack on the regulations. The major thrust of the dissent's complaint appears to be that although all of the evidence on which the Administrator relied was made available to the public at least three months before the regulations were issued, that evidence was not specifically delivered to or called to the attention of petitioners when it arrived at EPA. The dissent does not explain the origin of this supposed responsibility of the Agency. Certainly the APA's requirement of opportunity for notice and comment is satisfied by placing evidence in a designated public access file and repeatedly announcing the existence and location of that file in the FEDERAL REGISTER. *See* note 99 *supra*. Thus the dissent's chart of the availability of new evidence, dissent at 49, is fundamentally misleading. All interested parties had legally adequate notice of the evidence relied on by the Administrator, and of his intent to rely, *see* note 99 *supra*, from the time that evidence was placed in the public file.

The dissent attempts to avoid this fact by repeatedly lamenting that EPA's public file was "poorly indexed" (and dusty). Dissent at 20 n.34, 27, 45-47. On examination this entire attack turns out to be based on the excuse offered by EPA's attorney for a slight delay in providing a document to this court. *See id.* at 20 n.34. Had petitioners complained that they were not able to use the public file, we would of course have treated that complaint as a serious matter. But

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ies, alleging they were not made available for comment. A brief review of the record relating to these studies demonstrates that this attack is without merit.

1. *The Pilot Lead Isotope Study.* The pilot lead isotope study consists of two separately reported experiments which produced similar results.[103] One of these experiments was presented in a paper delivered at the October 1-2, 1973 Conference on Low Level Lead Toxicity sponsored by EPA and HEW and has apparently not been published elsewhere. However, the results of this experiment were reported to EPA in a letter dated August 28, 1972, and placed in the public file at that time. Doc. 875.[104] More significantly, a draft report of the companion experiment was received by EPA and placed in the public file in early May of 1973. Doc. 470, dated May 5, 1973. The final version of this study, which was eventually published in November 1973, was made avail-

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petitioners made no such allegation, nor did they suggest that EPA's public file procedures were in any way less adequate than the procedures customarily followed by administrative agencies. It may well be that the public reference procedures of this still relatively new agency can be improved. But we see no basis for a hypothesis, really a speculation, that persons affected are so unable to use the public file that minimal fairness is lacking. In any event that complaint was not made by able and experienced counsel for petitioners.

[103] Rabinowitz *et al.*, "Study of human lead metabolism using stable isotope tracers," paper presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C., Oct. 1-2, 1973, JA 678; Rabinowitz *et al.*, "Lead Metabolism in the Normal Human: Stable Isotope Studies," 182 SCIENCE 725-727 (1973), JA 704.

[104] *See also* EPA letter of Oct. 2, 1975. That letter and a letter of Sept. 26, 1975 were responses to requests for information from this court. Copies of these letters were sent by EPA to counsel for all parties to this litigation. No party commented on either letter.

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able to Ethyl and placed in the public file in early August 1973.[105] Thus the pilot lead isotope study was available for comment and criticism well before the regulations were promulgated.[106]

2. *The Unpublished Japanese Study.* The dissent places great stress on the fact that this unpublished and undated draft [107] bears an inscription prohibiting citation or quotation. Dissent at 21. We note first that since the study was prepared and submitted to EPA by the International Lead Zinc Research Organization, an industry group including these petitioners, Government Supp. Br. at 46, their claim of prejudice from the Administrator's use of the study rings false. Moreover, the study was placed in the public file and sent to petitioner Ethyl

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[105] The final draft was received by EPA's Office of the General Counsel Aug. 6, 1975, for transmittal to Ethyl, *see* note 117 *infra*, and to the public file. EPA letter of Sept. 26, 1975.

[106] Nalco Chemical Co. submitted extensive comments on the scientific evidence, including comments directed specifically at the lead isotope study, on Nov. 19, 1973. Doc. 821 at 7. Ethyl also submitted comments on this study in the form of a transcript of the October conference. Doc. 433.

The dissent finds it strange that we consider this transcript a substantive comment on the studies discussed at the meeting. Dissent at 41, 45. In response, we simply note that the only possible interpretation of Ethyl's action in preparing and submitting the transcript was that the company wished to have the critical comments of its scientists and some others who attended the meeting brought to EPA's attention as substantive critiques of the studies. A covering letter from Ethyl's counsel which accompanied the company's submission of the transcripts of a Feb. 26 and a March 15 meeting explicitly states this purpose. *See* JA 986.

[107] Tsuchiya *et al.*, Study of Lead Concentrations in Atmosphere and Population in Japan (undated), JA 1092.

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some four months before the Administrator's decision was announced.[108]

3. *The Chamber Study.* The dissent attempts to build an argument from the fact that the Second Health Document cites the chamber study [109] as a "preprint" whereas the Third references the study to the printed proceedings of the international symposium at which the paper was delivered. Dissent at 22, 28. *But see id.* at 23. However, comparison of the "preprint" with the final publication shows that they are absolutely identical.[110] Thus the chamber study was in the public realm from the beginning of the formal comment period on the reproposed regulations.

4. *The Seven Cities Study.* The dissent criticizes only the Administrator's reliance on an EPA reanalysis of the data on which this study was based, since it is conceded that the study itself [111] was available at the

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[108] The study was received by EPA's Office of the General Counsel on July 22, 1973, for transmittal to Ethyl, *see* note 117 *infra*, and to the public file. EPA letter of Sept. 26, 1975. It too was commented on by Nalco. Doc. 821 at 7. Since the study was available for comment four months prior to issuance of the Administrator's decision, we find the significance of the fact that it was not cited in the Third Health Document, dissent at 22, mystifying.

[109] Knelson *et al., Kinetics of Respiratory Lead Intake in Humans*, PROCEEDINGS OF THE INTERNATIONAL SYMPOSIUM ON ENVIRONMENTAL ASPECTS OF LEAD 391-401 (1973), JA 596.

[110] *Compare* Doc. 85, JA 596-601, *with* Doc. 111 at 391-401. The final printed "version" differs from the "preprint" only in that the former contains a translation of the authors' summary into French and German.

[111] Tepper & Levin, "A Survey of Air and Population Lead Levels in Selected American Communities," Department of Environmental Health, College of Medicine, University of Cincinnati, Cincinnati, Ohio (1972), JA 840.

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beginning of the formal comment period. Dissent at 22-23, 28-29. Three facts vitiate this criticism of the Administrator's reliance on the Seven Cities Study. First, the dissent is simply incorrect when it implies that the Administrator relied only on the "additional analysis." Dissent at 28. The Administrator actually relied primarily on a finding reported in the original study. *See* page 86 & note 92 *supra*. The reanalysis merely reconfirmed the validity of that finding.[112] Second, the

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[112] The dissent's emphasis on the importance of the reanalysis of the Seven Cities Study appears to be based on a misunderstanding of the meaning of statistical significance. Statistical significance simply expresses the level of assurance we can have that certain data was not the product of random relationships. *See, e.g.*, F. MOSTELLER, R. ROURKE & G. THOMAS, PROBABILITY WITH STATISTICAL APPLICATIONS 304-307 (2d ed. 1970).

> Unfortunately, the word "significant" in everyday use means not only "suggestive" but also "important" and "weighty". We do not carry these everyday meanings over into statistics. * * * A statistically significant result is one that the data support as showing a real effect, as opposed to a result that might readily arise from sampling variation.

Id. at 307.

Typically, scientists refuse to certify an observed relationship as "significant" unless they are 95% certain that the data could not have been generated randomly. *See* note 58 *supra*. Thus the authors of the Seven Cities Study found the relationship between air and blood lead levels between cities "[n]ot significantly different from 0 at the 5% level," JA 902, meaning that they could not be certain that if there were no genuine relationship in the real world, the relationship that was observed in this study would be found in at most five out of every 100 randomly drawn data samples. On reanalyzing the data using more refined techniques, EPA's scientists determined that the observed relationship could be expected to be produced by chance less than one time out of 1,000. *See* Doc. 228 at Table 3. Similarly, the authors of the Seven Cities Study themselves recognized the implication of their "consistent

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reanalysis itself is just EPA's effort to reexamine the study in light of the critical comments received on it.[113] It would be unreasonable to require another formal comment period whenever an agency determines that comments received during a preceding comment period do not undermine the validity of a particular piece of evidence. Finally, EPA made the reanalysis public in February 1973.[114]

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observation" that blood lead levels were higher in a given metropolitan area's urban region than in its suburbs. *See* p. 86 & note 92 *supra*. The reanalysis simply demonstrated that this "consistent observation" has less than a one in 1,000 likelihood of being the product of chance. *See* Doc. 228 at Table 3.

There is, of course, no reason why the Administrator cannot rely on observed relationships among data which he is less than 95% certain reflect a true underlying relationship between the phenomena that the data measure. *See* note 58 *supra*. The dissent's assertion that only the reanalysis provides support for the Administrator's decision assumes that the Administrator must be 95% certain before he credits any evidence.

[113] The purpose and contents of the reanalysis are described by its first sentence: "This brief paper is an attempt to answer questions raised by reviewers about the statistical analyses performed [in the Seven Cities Study]." Doc. 228 at 1.

[114] The results and methodology of the reanalysis were presented and discussed at a meeting of the EPA Hazardous Materials Advisory Committee on Feb. 26, 1973. JA 989-992. Representatives of Ethyl attended the meeting, prepared a transcript of it, including critical comments by some of those in attendance, and forwarded the transcript to the Administrator. JA 985; *see* note 106 *supra*. The dissent strives mightily to show that the reanalysis was not in the public domain until four days after the close of the formal comment period, rather than 13 days before. Dissent at 23. Even if this were true, the important point is that the reanalysis was available for public comment some nine months prior to issuance of the regulations.

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5. *The Newark, Rochester, Philadelphia, and Chicago Studies.* The only clear references to these studies,[115] which bear on the validity of the dustfall hypothesis, occur in a portion of the Administrator's decision that addresses the question, "What new information has become available since reproposal of the regulation and as a result of the additional comment period?" JA 5. This section of the decision follows the Administrator's explanation and justification of his conclusion that "lead particle emissions from motor vehicles present a significant risk of harm to the health of urban populations, particularly to the health of city children." JA 2. *See* JA 2-5. The Administrator was required to take account of the new information by the statute, which directs him to consider "*all* relevant medical and scientific evidence available to him." Section 211(c)(2)(A), 42 U.S.C. § 1857f-6c(c)(2)(A) (emphasis added).

Moreover, as the Administrator's placement of the discussion of these studies makes clear, the studies are not needed or used to support the conclusion that the dustfall hypothesis is reasonable. That conclusion is a

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[115] Margulis *et al., Residential Location, Ambient Air Lead Pollution and Childhood Lead Poisoning,* — ARCH. ENV. HEALTH — (in press at time record was compiled), JA 626; Sayre *et al., House and Hand Dust as a Potential Source of Childhood Lead Exposure,* — AM. J. DIS. CHILD — (in press at time record was compiled); and Vostal *et al.*, "Lead Containing House Dust: Another Source of Increased Lead Exposure in Inner City Children," paper presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C., Oct. 1-2, 1973, JA 720, 738; Needleman & Shapiro, "Dentine Lead Levels in Asymptomatic Philadelphia School Children: Subclinical Exposure in High and Low Risk Groups," paper presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C., Oct. 1-2, 1973, JA 662; Sachs, "Effects of a Screening Program on Changing Patterns of Lead Poisoning," paper presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C., Oct. 1-2, 1973, JA 718.

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sufficient basis for regulation under the statute. *See* pages 16-36, 90 *supra*. These additional studies, which are corroborative of the dustfall hypothesis, *see* pages 91-93 *supra* and Appendix B to this opinion, play no role in the Administrator's decision to regulate.[116]

Finally, petitioners and the dissent suggest that even if all the new studies were made available to the public for comment well before the Administrator reached his decision, Section 4 of the APA requires still another procedural step: that the Administrator, before arriving at his decision, publicly identify the recently received studies and comments on which he intended to rely so that the public might have yet another opportunity to comment on that material. If this new round of comments provided any significant information, the Administrator would presumably be able to use that information only if he formally stated his intent to do so and allowed still another round of comments. For obvious reasons, there is no support for this novel suggestion in the Act or in the jurisprudence.[117]

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[116] *Compare* JA 1-5 (the text of the Administrator's decision) *with* JA 186-193 *and* JA 231-239 (discussions of the dustfall hypothesis in the Second Health Document).

[117] The dissent cites no authority at all in that part of its argument which focuses on the asserted need for notice of intent to rely. *See* dissent at 31-32, 42-50. The authorities cited in the same section of the dissent, *see id.* at 33-35 & nn.78-80, support only the proposition that an agency may not keep secret the purpose of its proceeding or information important to its decision. The citation to K. DAVIS, ADMINISTRATIVE LAW TREATISE § 15.10 at 402 (1958), dissent at 34 n.78, refers to a discussion of the "Procedures for Using and Challenging Extra-Record Facts" of which an administrative decision maker has taken notice during an adjudicatory proceeding. Since all of the studies at issue here were disclosed by the Administrator as soon as they became available to him, not kept secret, and since there could be no allegation that any of this material was not part of the record properly be-

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The record in this case clearly demonstrates that EPA fully satisfied the requirements of administrative due process. In fact, EPA's efforts to elicit informed comment on its proposed action went far beyond the measures it was required to take. All health-related documents, including internal EPA policy memoranda, were made public upon receipt,[118] and comments on the documents

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fore the Administrator, these authorities are of no assistance to the dissent's argument.

Bowman Transportation, Inc. v. *Arkansas-Best Freight System, Inc.*, *supra* note 73, *quoted*, dissent at 35, also offers no support for the proposition that the APA requires notice of what material received and made public after publication of a proposed rule will be relied on to support the final regulation. In the first place, *Bowman* was an adjudicatory proceeding, not a notice-and-comment rule-making. More importantly, in the sentence immediately following the language quoted by the dissent the Supreme Court noted that a party's right "to be apprised of the factual material on which the agency relies for decision" does "not preclude a factfinder from observing strengths and weaknesses in the evidence that no party identified." 419 U.S. at 288 n.4. The Administrator's treatment of the Seven Cities Study, as well as of the Japanese study submitted by lead industry opponents of the proposed regulation, fits squarely within this observation. Moreover, the *Bowman* Court also noted that the petitioners there "are not in a position to claim unfair surprise" because the Commission had offered the same rationale for its interpretation of evidence in a case decided at the time the hearings in *Bowman* were beginning. *Id.* at 289 n.4. That rationale, it should be noted, was potentially rebuttable. In the face of this conclusion, the assertion that petitioners were not on notice that the agency might rely on information in the public record of this rule-making proceeding appears frivolous.

Finally, we note that nothing in Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 CORNELL L. REV. 375 (1974), supports the dissent's attempt to transmute the *three-step* process established by § 4 into a potentially unending and fruitless series of notices, comments, and notices of intent to rely on comments.

[118] *See* note 99 *supra*. Indeed, petitioner Ethyl was directly furnished with all such documents as a result of a Freedom

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were accepted until the date of final promulgation.[119] These documents included drafts of the Administrator's decision whose contents were very similar to the version finally published [120] and a draft of the Third Health Document which was substantially identical to the final draft.[121] Both the draft of the Administrator's decision and the regulations and the draft of the Third Health Document were circulated for comment, and comments were received [122] and acted upon.[123] On this record, we

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of Information Act, 5 U.S.C. § 552 (1970), suit. JA 1509-1510. *See Ethyl Corp.* v. *EPA*, 478 F.2d 47 (4th Cir. 1973).

[119] The dissent's effort to demonstrate that little comment was received about the most recent of the studies relied on by the Administrator is irrelevant. All the APA requires is that there have been an opportunity to comment. The three months between the time the important new studies were placed in the public file and the time of the Administrator's decision is clearly sufficient opportunity.

[120] JA 1474; JA 1502.

[121] Doc. 141. Chapters I, II, V, VII, and VIII (the conclusions) of this draft, dated Oct. 19, 1973, differ only in minor wording changes from the final Third Health Document. Chapters III, IV, and VI of the final version contain a few additional inconsequential paragraphs and references. The cover of the Oct. 19 draft states that "[i]t is being circulated for comment on its technical accuracy and policy implications."

The early October preparation and circulation of a draft decision and a draft Third Health Document, both in obviously near final form, belie the dissents' contention that this court's 30-day order, *see* p. 14 *supra*, forced EPA to rush into a decision it was not yet ready to make.

[122] *See, e.g.*, JA 2577 (Treasury Department comments); JA 2651 (letter from Secretary of Transportation); JA 2493 (Department of the Interior comments, dated Dec. 7, 1973). The Nalco comments, *see* note 106 *supra*, were addressed to both the draft Third Health Document and the draft of the Administrator's decision.

[123] *See* Ethyl letter dated Oct. 29, 1973, Doc. 1090, presenting evidence considered in the Third Health Document, JA 79

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cannot find that petitioners were deprived of administrative due process by EPA procedures.[124]

(ref. 11) & 140 (ref. 43). The Ethyl letter called this evidence to EPA's attention because "[t]o our knowledge these highly significant articles have not been referred to by EPA to date in its consideration of the health question * * *." Doc. 1090 *supra*. The timing of this letter suggests that Ethyl was referring to EPA's failure to reference these articles in the Oct. 19 draft of the Third Health Document. Ethyl would have received that draft due to its Freedom of Information Act suit. *See* note 118 *supra*.

[124] Beyond their attacks on the Administrator's interpretation of the statutory language, the evidence, and the procedures, petitioners raise a host of other objections to the final EPA regulations. We have considered above petitioners' claims that the Administrator did not properly consider the possibility of regulation under § 202, *see* note 66 *supra*, and that he did not make a valid finding that any substitute additive would be less dangerous than lead, particularly in light of his recent suspension of 1977 statutory emission standards. *See* notes 67-68 *supra*. *Cf.* note 2 *supra*. We shall briefly address petitioners' remaining contentions.

Ethyl claims a right to cross-examine agency witnesses. Ethyl Br. at 55. Not only does the Clean Air Act not require any hearings at all, but even if hearings were required cross-examination is not mandated in § 4 type proceedings, 5 U.S.C. § 553. *United States* v. *Florida East Coast R. Co.*, 410 U.S. 224, 240 (1973). Petitioners were afforded a meaningful opportunity to be heard and to controvert the evidence. Fairness demands no more. *See International Harvester Co.* v. *Ruckelshaus*, 155 U.S.App.D.C. 411, 427, 478 F.2d 615, 631 (1973).

PPG, duPont and NPRA claim the Administrator was required to set ambient air standards for lead under § 108, 42 U.S.C. § 1857e-3, before acting under § 211, and his failure to do so warrants reversal. PPG/duPont Br. at 45; NPRA Supp. Br. at 37-47. There is no basis in the statute for this claim. While § 211 expressly mentions consideration of regulation under § 202, it makes no mention at all of § 108. Moreover, the Administrator claims, with some statutory support,

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V. Conclusion

The complex scientific questions presented by this rulemaking proceeding were "resolved in the crucible of debate through the clash of informed but opposing scien-

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that action under § 108 is discretionary with him. 38 Fed. Reg. 33740 (1973). *Cf.* note 21 *supra.*

Nalco, PPG and duPont all claim that the Administrator did not give sufficient consideration to the adverse economic effects of his decision to regulate lead additives. Nalco Br. at 42; PPG Br. at 40. Even if the Administrator is allowed to consider at all the economic effects of regulations issued under § 211(c)(1)(A), a question we do not address, he has plainly both well understood and considered the consequences of these regulations and found them to be minimal. 38 Fed. Reg. 33739 (1973). We cannot say his judgment was irrational.

NPRA objects to the Administrator's switch from leaded pool averaging to total pool averaging. NPRA Supp. Br. at 47-48. EPA switched in response to the comments of a majority of refiners. 38 Fed. Reg. 33739. We find nothing wrong with the use of that system. We discussed at note 100 *supra* the propriety of the Agency's announcing this change when promulgating its final regulations.

Lastly, Ethyl, PPG, duPont and NPRA claim that EPA was required to file an environmental impact statement under § 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. § 4332(2)(C) (1970), or the functional equivalent of one. Ethyl Br. at 57; PPG Br. at 46; NPRA Br. at 53. So far as EPA regulation under § 211 is concerned, we answered this question in *Amoco*, and recent legislation has made the point doubly clear. An environmental impact statement from EPA does not appear necessary; a "functional equivalent" suffices. The *Amoco* court held that when the Administrator has considered the evidence and alternative courses of action required before action under § 211 is permitted, he has necessarily furnished the "functional equivalent" of an impact statement. *Amoco Oil Co.* v. *EPA*, *supra* note 2, 163 U.S.App. D.C. at 189-190, 501 F.2d at 749-750. Since we believe the Administrator has complied with all the demands of § 211 in this case, we believe he has likewise complied with NEPA.

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tific and technological viewpoints." *International Harvester Co.* v. *Ruckelshaus*, 155 U.S.App.D.C. 411, 448, 478 F.2d 615, 652 (1973) (concurring opinion of Chief Judge Bazelon). On January 31, 1971 the EPA began the debate by publishing advance notice of proposed rulemaking concerning possible controls on lead additives in gasolines because of their possible danger to health. On February 23, 1972 it published the proposed regulations supported by a document, *Health Hazards of Lead* (First Health Document), prepared by the EPA scientific staff. It invited comment from the lead industry, the scientific community, and the concerned public. The EPA held public hearings in Washington, D.C., Dallas, and Los Angeles to give people across the country an opportunity to join the debate.

On January 10, 1973 the EPA reproposed the regulations in slightly changed form, supported by a Second Health Document which reflected the scientific comments on the first and brought the scientific information on the subject up to date. Scientific studies, pro and con, which had become available since the proposed regulations were first published were included. Again the EPA invited the parties, the scientific community, and the concerned public to comment. Finally, on November 28, 1973, almost three years after the debate was joined, the EPA promulgated its regulations accompanied

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Any lingering doubt in this regard has been removed by recent congressional action. The Energy Supply and Environmental Coordination Act of 1974, Pub. L. No. 93-319, 88 STAT. 246 (1974) (codified at 15 U.S.C. § 791 *et seq.* (Supp. IV 1974)), provides: "No action taken under the Clean Air Act shall be deemed a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969." *Id.* § 7(c)(1), 15 U.S.C. § 793(c)(1). Thus Congress has expressly exempted EPA action under the Clean Air Act from NEPA's environmental impact statement requirement.

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by a 10,000-word opinion, thoroughly and comprehensively analyzing the various scientific studies and giving its reasons why it resolved the scientific debate it had provoked in favor of protecting the public from the danger of lead emissions. A Third Health Document, extensively detailing and reviewing the current state of scientific knowledge of the health effects of airborne lead, also accompanied the regulations and the reasons for their issuance.

Because of the importance of the issues raised, we have accorded this case the most careful and exhaustive consideration. We find that in this rule-making proceeding the EPA has complied with all the statutory procedural requirements and that its reasons as stated in its opinion provide a rational basis for its action. Since we reject all of petitioners' claims of error, the Agency may enforce its low-lead regulations.

Affirmed.

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APPENDIX A

Evidence Relating to the Administrator's Conclusion That Automobile Lead Emission Products Are Directly Absorbed in the Body to a Significant Extent.

1. *Experimental Calculations.* The Administrator leads off his discussion of the relationship between airborne and blood lead levels with a set of calculations based on the experimental work of Kehoe and designed to provide a rough estimate of the dangers posed by exposure to various ambient air lead concentrations. Third Health Document, V-2 to V-9, JA 82-89. Kehoe, in his classic Harben Lectures,[1] reported on his work in supplementing the daily lead intake of various subjects by differing amounts of lead and carefully measuring their blood lead levels over time. Subject S.W.'s normal dietary intake of 300 ug lead was supplemented by an additional 300 ug, and this total daily dietary intake of 600 ug brought him to a blood lead level of 40 ug. Since the 40 ug mark is EPA's warning level, the Agency sought to calculate, based on Kehoe's data, the amount of airborne lead needed to be absorbed to reach this level.

These calculations start with the absorption figures for ingested lead. Commonly accepted data for daily dietary intake for adults are on the order of 200-300 ug/day, with ranges of 100 to 500 ug/day. Of this amount, 10 percent is thought to be absorbed into the blood; the remainder is excreted. Thus the 600 ug daily intake of subject S.W. caused a daily absorption of 60 ug into the blood. If daily dietary lead intake averages 200-300 ug, for a daily absorption of 20-30 ug, what air lead exposure level, asked EPA, could result in an increased absorption of 30-40 ug daily, so that total

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[1] R. KEHOE, THE METABOLISM OF LEAD IN MAN IN HEALTH AND DISEASE: THE HARBEN LECTURES (1960), *reprinted from* J. ROYAL INST. PUBLIC HEALTH HYG. 1961, JA 500.

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absorption remained 60 ug? Third Health Document at V-6, JA 86.

Absorption of respiratory lead is dependent on three factors: air lead concentration, volume of air inhaled daily, and percent of inhaled lead absorbed. EPA based its calculations on daily respiration of 15 and 20 cubic meters (m^3), and absorption of 17, 30, and 37 percent of the lead in the respired air. By this process, the Agency calculated that a "standard" man, who breathes 20 m^3 of air daily, and absorbs 30 percent of the lead in the respired air would absorb 30 ug of lead daily if exposed to air lead concentrations of 5.0 ug/m^3, a concentration found in parts of several of our larger cities. At this rate of respiratory absorption, a subject absorbing 30 ug of dietary lead daily would reach a blood lead level of 40 ug within a year. Third Health Document at V-4 to V-7, Figures V-1 & V-2, Tables V-1 to V-4, JA 84-87, 89-103.

These calculations suggest that the danger from lead emissions in the atmosphere is a real one. If substantiated, they warn that air lead concentrations can make a significant contribution to blood lead levels. Two clinical studies, which will be discussed in detail below, have recently provided important empirical support for this theoretical conclusion. The chamber study, *see* pages A-16 to A-18 *infra*, analyzed subjects with low dietary lead intake (approximately 100 ug/day, or 10 ug daily absorption) but high respiratory intake (approximately 49-60 ug daily absorption[2]). The blood lead level of the experimental subjects went from 20 ug to 37 ug in a four-month period. These results are similar to those predicted by the above calculations at such elevated ex-

[2] The absorption data is based on an estimated 15 m^3 daily respiration (since the subjects were sedentary), 30-37% absorption of lead from air, and a lead concentration of 10.9 ug/m^3. Third Health Document at Table V-5, JA 104.

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posure. Third Health Document at V-8 & Table V-5, JA 88 & 102. The pilot lead isotope study, *see* pages A-16 to A-17 *infra*, demonstrated that in an atmosphere of 2 ug/m^3, 28 percent of a subject's lead intake was attributable to respiratory lead. This closely corresponds to the calculations made for a "standard" man in such an atmosphere; EPA's predicted value at 2 ug/m^3 was 29 percent. *Id.* at V-3 & Table V-1, JA 83 & 100. Thus the theoretical calculations, supported by the empirical data, provide substantial support for the Administrator's conclusion that absorption of airborne lead makes a significant contribution to the body lead burden.

Petitioners' attack on the Administrator's analysis is so misguided that it is questionable whether they have even attempted to understand the purpose of these calculations. Instead, they fight again a battle they won over two years ago. Petitioners vigorously attack the Administrator's calculations as a revitalization of the so-called Goldsmith-Hexter regression equation. Nalco Supp. Br. at 39-40; PPG/duPont Supp. Br. at 32-33. As they rightly observe, EPA abandoned this approach at the time of the Second Health Document. *See* Second Health Document, Appendix A, JA 214-218. Petitioners do not recognize, however, that the mere fact the Administrator is once again engaged in theoretical calculations does not necessarily mean he has returned to the discredited Goldsmith-Hexter approach.

The Goldsmith-Hexter regression equation was an attempt by EPA to predict a person's blood lead level as a direct function of the air lead concentration to which he was exposed. This equation would then be used to find a "safe" air lead concentration to avoid elevated blood lead levels. First Health Document at 3-5 & Table 7, JA 294-296, 305. The approach simply made too many assumptions. In particular, it did not recognize the wide variability of dietary lead intake and thus was of no

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predictive value. After considering petitioners' critiques, EPA abandoned its attempt to quantify a safe level of exposure and settled on its current, more qualitative, approach to the evidence. JA 214-218.

The current analysis is much more modest in scope and does not rely *at all* on the Goldsmith-Hexter data or equation. Well established work has shown that blood lead levels will reach the 40 ug mark if a daily absorption of 60 ug is maintained over time. EPA simply calculates, for various specified situations, the air lead concentrations necessary to produce that daily 60 ug absorption figure. Since petitioners' objections are not addressed to this use of the Kehoe data, they can hardly be credited.[3] On the other hand, use of predictions based on uncertain data is plainly within the scope of the precautionary "will endanger" standard. *Amoco Oil Co.* v. *EPA*, *supra*, 163 U.S.App.D.C. at 181, 501 F.2d at 741. And since in at least half the situations considered by EPA an elevated blood lead level would be produced in a "standard" man by airborne lead levels now present in parts of our urban environments, we cannot say the Administrator's reliance on this data, as bolstered by the clinical studies, was irrational.

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[3] Petitioners' second objection is likewise without merit. Nalco claims EPA improperly assumes a straight-line correlation between air lead exposure and blood lead levels, and quotes EPA scientists:

> The best fit for these [Kehoe] data may be curvilinear rather than a linear function, in which case, blood leads would level off about 40 ug/100 g rather than continuing to increase indefinitely.

JA 85, *cited in* Nalco Supp. Br. at 39. The EPA calculations, however, make just the adjustment suggested (which is hardly surprising since the suggestion appears in the Third Health Document). EPA calculates only the air lead levels necessary, under various circumstances, to bring blood leads to 40 ug—and no higher. Whether or not blood lead increases plateau thereafter is of no consequence for these calculations.

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2. *Epidemiological Studies.* The intercity correlations produced by the major epidemiological study, the Seven Cities Study, were negative. The Study was an attempt to correlate atmospheric and body lead levels in seven cities in the United States. No statistically significant correlation was found between the atmospheric lead in a city and the blood lead level of its inhabitants. As the Administrator noted in promulgating the low-lead regulations, residents of New York City had lower average blood lead levels than residents of Philadelphia, despite the fact that somewhat higher airborne lead levels were measured in New York. 38 FED. REG. 33735.

Petitioners rely heavily on the negative conclusion of the Seven Cities Study. PPG duPont Supp. Br. at 24-25; Nalco Supp. Br. at 34-35; NPRA Supp. Br. at 11-12; Ethyl Supp. Br. at 45-46. The Administrator, however, discounted the significance of the Study's overall conclusion because of the intercity differences in lead intake from sources other than the air, 38 FED. REG. 33735, and instead relied on data in the study relating to individual metropolitan areas. In such areas climate was constant [4] and it could more readily be assumed that the lead content of the diet was roughly comparable for all subjects, so that dietary lead's confounding influence on the data would be minimized. These data showed consistent differences between the blood lead levels of urban and suburban dwellers, with the urban residents, who

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[4] Climate may influence both air lead levels and exposure to lead. Greater wind speed is associated with lower air lead levels, and higher readings have been associated with surface inversions. JA 854, 873. Climate also influences the amount of time spent exposed to atmospheric lead outdoors, the time spent indoors with windows open (which increases lead exposure) or air conditioners on (which decreases lead exposure). JA 400, 467. *See* note 11 *infra*. For these reasons, it may be preferable to compare blood lead levels of persons exposed to roughly similar climates.

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were exposed to higher air lead concentrations, invariably showing higher blood lead levels. The authors of the Seven Cities Study concluded:

> In a given metropolitan area, urban-suburban comparisons tend to minimize the influence of diet and climate. That airborne lead contributes to the relatively higher blood lead concentrations in center-city populations would seem to be the most probable interpretation of this consistent observation.[5]

JA 892. Upon reanalysis of the underlying data, the Administrator concluded that while air lead was not the most influential factor affecting urban-suburban blood lead levels, it was a significant factor. 38 FED. REG. 33735; Third Health Document at V-9, JA 89. Petitioners do not so much attack the Administrator's reliance on this data as they argue that the intercity comparisons of the Study should be accepted. In this context, we cannot say that the Administrator's statement of reasons for crediting the suburban-urban data while discounting the intercity data was irrational.

For reasons similar to those advanced for discounting the intercity results of the Seven Cities Study, the Administrator also gave only slight value to the intercity

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[5] PPG and duPont argue that this conclusion is contradicted by the Philadelphia data in the Seven Cities Study. Philadelphia urban-suburban data were analyzed twice, they argue, and the second analysis turned the result around, producing higher blood lead values for suburban dwellers than for city dwellers. PPG/duPont Supp. Br. at 25. In fact, the data were analyzed *three* times, the first time in the Seven Cities Study itself, JA 901 (Ardmore and Rittenhouse data), and the second and third times in a submission prepared for EPA by duPont. Only on the third analysis did the turn-about result. JA 2211. Thus two out of three analyses of the Philadelphia data (one by duPont), as well as the data for the other two cities, support the Administrator's position. We cannot say his conclusion is irrational.

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results of the duPont-sponsored Azar study[6] of five groups of 30 subjects—two groups of taxicab drivers and three groups of duPont employees—in four cities around the United States. This study is also strongly relied upon by petitioners to show the lack of a relationship between body and air lead concentrations. Nalco Supp. Br. at 35-36; PPG/duPont Supp. Br. at 26-27; NPRA Supp. Br. at 12. The subjects' exposure to air lead was monitored continuously for two to four weeks. As in the Seven Cities Study, no significant correlation was found between air lead concentration and body lead burden among all the subjects. Nonetheless, the Administrator noted that by the duPont scientist's own assessment the "design deficiencies" of the project included

> the use of different occupational groups, the use of different cities, data collection during different times of the year, lack of detailed histories and physicals, and perhaps most importantly, the lack of data relative to ingested lead intake.

JA 398-399. *See* Third Health Document at V-11, 12, JA 91-92.

While not according significant weight to the study for these reasons, the Administrator did observe a generally positive relationship between average blood lead values and increasing airborne lead exposure. Third Health Document at V-12, JA 92. *See* JA 396 (Fig. 3). This relationship is especially striking in the data for Los Angeles, the only city in the study in which two groups were evaluated. Taxi drivers exposed to air lead concentrations of 6 ug showed blood lead concentrations some 25 percent higher than office workers exposed to

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[6] Azar *et al., Relationship of Community Levels of Air Lead and Indices of Lead Absorptions,* in PROCEEDINGS OF AN INTERNATIONAL SYMPOSIUM ON ENVIRONMENTAL HEALTH ASPECTS OF LEAD, CEC, CID, Luxembourg, at 581-594 (May 1973), JA 387.

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air lead concentrations of 3 ug. JA 392 (Table 1). This finding, again assuming some rough dietary comparability, is consistent with the urban-suburban differences of the Seven Cities Study.[7]

The inferences the Administrator drew from the Seven Cities Study and the Azar study were bolstered by the preliminary results of a Japanese study[8] designed to duplicate the design technique of the Seven Cities Study. Analyzing exposure to air lead concentrations in a country whose concentrations of airborne lead, averaging 0.65 ug/m^3, are "*far less* than those observed in the U.S. cities," JA 1130 (emphasis added), the Japanese study reached an inconclusive result similar to that of the Seven Cities Study: "With the present level of lead concentration in the air it is difficult to establish any direct relationship between lead levels in the air and such levels in blood and urine." Id. 1131.

Nonetheless, once again the urban-suburban gradient clearly emerged. Even at that significantly lower air lead concentration, the study was able to find "a significant positive correlation between ambient [lead] level and blood level for workers by area," *id.* 1123, and to conclude that the increase of blood levels with urbanization "was statistically significant," although of small magnitude. *Id.* 1130. *See also id.* 1119, 1122-1123. Given

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[7] Nalco attempts to belittle this finding by claiming that it represents "a comparison of 6 cab drivers with 2 office workers A. 392)." Nalco Supp. Br. at 35-36. Nalco is distorting the record. The cited reference, Table 1 of the Azar study, JA 392, is explicitly headed "30 subjects per group." What Nalco is apparently referring to is a line reading, "Data Per Subject, ±Bloods: L.A. Cab, 6; L.A. Office, 2 * * * ." Contrary to Nalco's suggested reading, this line indicates only that the 30 taxicab drivers were given 6 blood tests each, while the 30 office workers were given only 2 blood tests each.

[8] Tsuchiya *et al., Study of Lead Concentrations in Atmosphere and Population in Japan* (undated), JA 1092.

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the low levels of air lead concentration throughout Japan, the small magnitude is hardly surprising; what is surprising is that the difference is significant at all. It is for this finding that the Administrator cited the study.

Petitioners are quick to point out that the authors observe:

> [W]ithout monitoring personal exposure, the urban-rural differential in blood lead may not be considered to reflect the differential in air lead concentration.

JA 1124. *See* Nalco Supp. Br. at 36; Ethyl Supp. Br. at 47. In context, however, the statement does not have the significance petitioners ascribe to it. The authors have just observed that although air lead concentrations are generally lower in rural areas than in the cities, pockets of high and low air lead concentrations may exist in both areas. JA 1123. Thus they simply caution that without firm proof of individual exposure to air lead it is improper to conclude with certainty that the urban-suburban gradient necessarily reflects air lead differentials. JA 1124. As has been observed above, however, inability to prove conclusively cause and effect relationships is an inherent limitation of epidemiological research. The authors' warning is proper and does not detract at all from a study of this nature. It is significant, however, that immediately after this warning, the authors suggest the proper inference to be drawn from the data, "No doubt an increased respiratory exposure will contribute to an increased intake of lead into the body," *id.* 1124, and conclude, "A positive correlation between the lead levels in air and blood was strongly suggested * * *." *Id.* 1131. We think petitioners have failed to show that the Administrator's reliance on this study was improper.

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Beyond the Azar and Seven Cities Studies, the only study affirmatively offered by petitioners to disprove the Administrator's conclusion is the London taxicab study, an epidemiological study of a much smaller group than any of the work discussed above. The study, conducted by Jones *et al.*,* compared smoking and nonsmoking day-shift taxi drivers with similar night-shift drivers, and found no significant blood lead differences between them. No attempt was made, however, to measure the exposure of these drivers to airborne lead; the authors assumed the daytime drivers were exposed to more lead since they showed higher carboxyhemoglobin levels, indicating exposure to exhaust fumes. Because of the failure to measure actual air lead levels, as well as to measure smoking intensity of the smoking drivers, the Administrator found the results of this study unhelpful (although, more than with the other studies cited by petitioners, dietary lead could be assumed to be relatively constant). Third Health Document at V-12, 13, JA 92-93. The validity of the data is particularly questionable in light of its inconsistency with the Azar data, also presented by petitioners, which showed significant differences between blood leads of taxi drivers and office workers in the same city that corresponded to significant differences in measured air lead exposure. We cannot fault the Administrator's discounting of the London taxicab study in light of the offsetting evidence to which he pointed.

The Seven Cities, Azar, and Japanese studies all were broadly based epidemiological work. Nonetheless, the Administrator found supportive evidence in all of them when he analyzed the data according to regions so that the effects of diet and climate could be, to the extent

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* Jones *et al.*, *Blood Lead and Carboxyhemoglobin Levels in London Taxi Drivers*, 2 LANCET 302 (Aug. 12, 1972), JA 498.

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possible, minimized. Perhaps the most important epidemiological study before him, however, was the Daines study,[10] which did not present the problems of the above studies since it was composed of two studies, each of a single neighborhood. In the first neighborhood studied, the researchers measured, over a two-year period, the blood lead levels of black females living 3.7, 38.1, and 121.9 meters from a major highway; air lead levels at these locations were 4.60, 2.41, and 2.24 ug/m^3 respectively. The results showed that women living 3.7 meters from the highway, in high air lead concentrations, averaged blood lead levels of 23.1 ug, while those at the greater distances, and lesser air lead concentrations, averaged 17.4 and 17.6 ug.[11] That is, *women living in air lead concentrations of 4.60 ug/m^3 had blood lead concentrations 32 percent higher than comparable women living in air lead concentrations 2.23 to 2.41 ug/m.*[3] While, as with an epidemological work, there were uncontrolled, and possibly confounding, variables, there were far fewer here than in any of the studies cited above, and the dramatic positive results suggest their effect was minimal.

Petitioners attempt to discredit the Daines study by pointing to the results of the second neighborhood studied. There the researchers studied, for a three-month period, white women living 33.5 and 457 meters from another major highway in air lead concentrations of 1.95 and 1.73 ug/m^3; these women showed blood lead levels of 15.7 and 16.1 ug respectively. Petitioners suggest this shows lack of relationship between air lead and blood lead, thus making the Daines results "equivocal," Nalco

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[10] Daines *et al.*, *Air Levels of Lead Inside and Outside Homes*, 41 INDUSTRIAL MED. J. 26 (Oct. 1972), JA 465.

[11] Among those women living 3.7 meters from the highway, both air lead and blood lead levels were significantly lower in homes that were air-conditioned. JA 467; Third Health Document at V-10, JA 90. *See* note 4 *supra*.

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Supp. Br. at 36. Because the average blood lead at the greater distance was slightly higher than at the closer distance, petitioners even suggest that the result shows a relationship opposite to that suggested by the Administrator, PPG/duPont Supp. Br. at 31-32. To the contrary, the Administrator found the results of this study completely consistent with the results of the first neighborhood studied, and concluded that the Daines study provided major support for his position.

We cannot fault the Administrator's analysis. The suggested inverse relationship is nonexistent. The slight difference between 15.7 and 16.1 ug was analyzed by Daines and found to be insignificant. JA 467. We have been shown no reason to believe his analysis was in any way improper. Meanwhile, the data correspond closely to those found in the first neighborhood at distances beyond 100 feet (approximately 30 meters). Since the study found the air lead levels decreased by over 60 percent after the first 100 feet, JA 465, it is not surprising that no significant differences were found in *either* of the two neighborhoods beyond that distance.[12]

The Administrator also drew some support from several studies conducted in communities housing lead smelters which, like automobiles, emit lead particulates into the atmosphere. One such study showed positive differences between children living in smelter and non-

[12] In both studies air lead concentrations were comparable and blood lead differences were insignificant at distances beyond 100 feet from the roadway. In the first study, at distances of 38.1 and 121.9 meters the air lead concentrations were 2.41 and 2.24 ug/m^3 and blood lead concentrations 17.4 and 17.6 ug. In the second study, at distances of 33.5 and 457 meters the air lead concentrations were 1.95 and 1.73 ug/m^3 and the blood lead concentrations 15.7 and 16.1 ug. All of this shows only that where air lead concentrations are essentially similar, there is no reason to anticipate differences in blood lead concentrations.

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smelter communities [13] and another quantified decreasing blood lead levels corresponding with increasing distance from the smelter.[14] Since neither study measured air lead concentrations, they could do no more than indicate in a qualitative way the relationship between blood lead levels and exposure to lead in air (and in dustfall). Third Health Document at V-13, JA 93. While petitioners argue that findings relating to inhalation of lead from lead smelters cannot be extrapolated to situations involving inhalation of automotive emissions, PPG/duPont Supp. Br. at 33. their arguments lack force given both the iimited nature of the Administrator's use of these studies and various toxicological studies indicating both types of lead to be comparably absorbed in experimental animals. 38 FED. REG. 33734, 33735; Third Health Document at VI-5, 6, JA 115-116.

These constitute the primary epidemiological studies before the Administrator. None of them attempted to control the important variable of dietary intake; such control would be impossible in a pure epidemiological study since controls destroy the "real life" nature of the experiment. Recognizing that diet is nonetheless a major factor in human lead intake, the Administrator sought data in which dietary lead could be assumed relatively constant among all subjects.[15] Thus he relied most

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[13] Hammer *et al.*, "Trace Metals in Human Hair as a Simple Epidemiologic Monitor of Environmental Exposure," TRACE SUBSTANCES IN ENVIRONMENTAL HEALTH V: A SYMPOSIUM 25 (D. Hemphill, ed. 1972).

[14] Nordman, *Blood Lead Levels and Erythrocyte Delta-Aminolevulinic Acid Dehydratase Activity in People Living Around a Secondary Lead Smelter*, 10 WORK—ENVIRONMENT—HEALTH 19 (1973).

[15] Petitioners accuse the Administrator of worrying about dietary lead intake only when it serves his purpose of discrediting a contradictory study, and conveniently ignoring

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heavily on urban-suburban data from the Seven Cities and Japanese studies, on intracity data from the Azar study, and on the Daines and smelter community studies. In this data base, a significant correlation between air lead and blood lead consistently emerged. We cannot find the Administrator's reliance on these data, and his rejection of the London taxicab study and the intercity results of the Seven Cities and Azar studies, to be arbitrary and capricious.

3. *Clinical Studies.* In the Albany chamber study [16] two groups of volunteer prisoners lived for weeks in a climate-controlled chamber where they were exposed to airborne lead levels of 10.9 ug/m^3 and 3.2 ug/m^3 for 23 hours a day. While dietary lead was not measured, a control group lived under similar conditions and was fed the same diet. The controls, however, were exposed to air lead concentrations of only 0.2 ug/m^3, thus making valid comparisons possible between groups. Blood lead concentrations did not change significantly among the controls during the experiment. JA 593 (Fig. 1). On the other hand, blood lead levels of those exposed to air lead concentrations of 3.2 ug/m^3 increased from 19 to 25 over an 11-week period. Even more dramatically, prisoners exposed to daily air lead concentrations of 10.9 ug/m^3 registered enormous blood lead increases: over

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the problem when he wants to use the data. Ethyl Supp. Br. at 52. In fact, however, the Administrator's concern is consistent. Dietary control is a problem in all the epidemiological studies. The Administrator consistently credits inferences derived from data in a single metropolitan area or where dietary absorption of lead can be deemed roughly constant. This is a principled approach to the evidence, and one which we approve.

[16] Knelson *et al.*, *Kinetics of Respiratory Lead Intake in Humans*, in PROCEEDINGS OF AN INTERNATIONAL SYMPOSIUM ON ENVIRONMENTAL HEALTH ASPECTS OF LEAD, CEC, CID, Luxembourg, at 391-401 (May 1973), JA 596.

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18 weeks, their average blood lead almost doubled, increasing from about 20 ug to 37 ug. Besides having independent significance, these results correlate closely to the Administrator's theoretical predictions of the effect of exposure to such high air lead levels. *See* pages A-2 to A-3 *supra.*

Petitioners argue that these results show little since exposure to even this high air lead level (twice that found in even the most polluted urban areas) did not cause the subjects' blood lead levels to pass the 40 ug warning point. PPG/duPont Supp. Br. at 30-31; Nalco Supp. Br. at 38. This argument misses the point. These subjects were exposed to high air lead concentrations for only 18 weeks; the Administrator, however, is concerned about the effects of exposure over a lifetime. The rapid rise of blood lead among the experimental subjects in this short period shows that air lead is a significant factor in the body lead burden and that the Administrator's concern may well be warranted. Petitioners' argument boils down to an objection that the study is flawed because it did not continue until the subjects were poisoned. We can hardly credit such a complaint.

Petitioners also argue that the study is suspect because the lead particulates to which the subjects were exposed were not identical to those emitted from automobiles. PPG/duPont Supp. Br. at 30; Nalco Supp. Br. at 38. It is true that the particles differed somewhat from those found in automobile exhausts. This was an inherent limitation in the study since atmospheric lead pollution could not be precisely reproduced in a laboratory, and the authors acknowledged it as such. Doc. 385 at 17. But while the absorption of lead in the experiment "may differ" from that due to exposure to the ambient air, *id.*, the study was, of course, designed to minimize any differences. Thus over 80 percent of the lead particles in the chamber were in the respirable range, JA 584, a

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figure that compares favorably with accepted data for lead particles in the ambient air, including data produced by petitioners' own Azar study (79-90 percent). JA 392 (Table 1). *See also* Third Health Document at II-8, JA 41. Moreover, the author of the study, when closely questioned about this point by an Ethyl witness after delivering his paper at an international lead conference in Amsterdam in 1972, suggested that the more complex lead particles present in automobile exhausts would nonetheless be absorbed in much the same way as the particles in the experiment. Doc. 111 at 399-401. The Administrator was aware of this limitation on the chamber study, but concluded that the differences in particle size "were sufficiently small so that inferences can be made regarding effects of airborne lead among the general population." Third Health Document at V-8, JA 88. Thus he considered petitioners' objection to this study and rejected it; we cannot say that rejection was arbitrary or capricious.

The second clinical study, the pilot lead isotope study,[17] was an ambitious attempt to measure precisely a subject's total intake and output of lead. A subject was placed for 160 days in a controlled metabolic unit where he was extensively monitored. He was fed a low-lead diet and lived in an atmosphere with a lead concentration of 2 ug/m^3, a level frequently found in our major cities. His diet included lead isotope tracers so that separation of dietary and respiratory lead was possible. Based on careful measurements of the quantity of isotope-

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[17] Rabinowitz *et al.*, "Study of human lead metabolism using stable isotope tracers," paper presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C., Oct. 1-2, 1973, JA at 678; Rabinowitz *et al.*, "Lead Metabolism in the Normal Human: Stable Isotope Studies," 182 SCIENCE 725 (Nov. 1973), JA 704. *See* Third Health Document at V-3, JA 83. *See also* 38 FED. REG. at 33735.

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labeled lead in the blood, the amount attributable to respiratory absorption could be derived. The researchers concluded that at 2 ug/m^3 air lead concentration the body absorbed approximately 15 ug of lead daily from the atmosphere, so that 28 percent of the subject's blood lead was a product of airborne lead. JA 705-706. This conclusion was replicated by preliminary results on a second subject. JA 690. Together with the chamber study, this study provides important experimental support for EPA's theoretical calculations discussed above, *see* pages A-1 to A-4 *supra*.

Certainly the project proceeds on some rough assumptions and presents data on only two subjects, as petitioners quickly point out, Nalco Supp. Br. at 38-39; PPG/duPont Supp. Br. at 27-28, and as the researchers freely conceded. JA 683, 684, 686, 688. The limited number of subjects would seem a necessary consequence of the intrusive, as well as confining and time-consuming, nature of the study. And the very magnitude of the air-blood correlation found, and the limited purpose to which the results were put—to support the independent theoretical calculations, Third Health Document at V-3, JA 83—convince us that the Administrator's reliance was not improper.

Petitioners also argue that the result is so inconsistent with the other evidence that it must be rejected. PPG/duPont Supp. Br. at 28; NPRA Supp. Br. at 12. To the contrary, the results are remarkably consistent with the evidence the Administrator credited—the Seven Cities and Japanese urban-suburban data, the Azar intracity data, the Daines study, the chamber study. All of these findings indicate a significant contribution of air lead to the body lead burden; a finding of a 28 percent contribution is consistent with that conclusion. The finding is only inconsistent with the data petitioners urged the

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Administrator to accept but that he, properly we hold, rejected.

The two clinical studies, then, provide important support for the Administrator's conclusion. They show that exposure to high airborne lead concentrations can lead to rapid increases in blood lead levels, and that respiratory absorption of lead accounts for a significant amount of the body lead burden. These findings are consistent with the theoretical calculations and support the clear inference of the many epidemiological studies.

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APPENDIX B

Evidence That Lead Dustfall from Automobiles is Swallowed by Children with Pica.

To support his conclusion that children with pica swallow dust contaminated by lead from automobile emissions, the Administrator relied on studies showing that a persistent fraction of children with lead poisoning had no contact with leaded paint, thereby implicating another source.[1] Other work found a small but significant number of children living in good housing with no apparent exposure to lead paint to have, nonetheless, high lead levels, again suggesting another source.[2] Meanwhile, there is evidence tying children to leaded dust. A Rochester, New York study found lead-containing dust on the hands of inner city children with elevated blood lead levels and suggested the hand-to-mouth route as a significant source of lead exposure.[3] A study in Charleston,

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[1] *See, e.g.*, NYC Bureau of Lead Poisoning Control, data submitted to EPA Aug. 31, 1972 & Sept. 12, 1972, Doc. 104; Lepow, testimony before Subcommittee on the Environment, Senate Committee on Commerce, May 8, 1972, *cited in* Second Health Document at V-18, JA 196.

[2] Personal communication from M. Dea, Department of Human Services, Multnomah County, Oregon, to K. Bridbord, EPA, dated March 6, 1973, Doc. 44; Gilsinn, Estimates of the Nature and Extent of Lead Paint Poisoning in the United States, NBS Technical Note 746, Dec. 1972, Doc. 61; Needleman & Shapiro, "Dentine Lead Levels in Asymptomatic Philadelphia School Children: Subclinical Exposure in High and Low Risk Groups," presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C. (Oct. 1-2, 1973), JA 662.

[3] Sayre *et al.*, *House and Hand Dust as a Potential Source of Childhood Lead Exposure*, — AM. J. DIS. CHILD — (1973) (in press at time of insertion in record), JA 720; Vostal *et al.*, "Lead Analysis of the House Dust: A Method for the Detection of Another Source of Lead Exposure in Inner City

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South Carolina found that children living in homes near high lead soil concentrations had higher blood levels than children in randomly selected homes.[4] Epidemiological

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Children," presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C. (Oct. 1-2, 1973), JA 738.

Since only 58% of the inner-city households had lead-based paint, lead paint chips were discounted as the sole source of elevated lead levels. The study made no attempt to determine "whether the lead comes from airborne sources, chalking of paint, or from paint chips shed from walls and perhaps pulverized underfoot." JA 732.

[4] The authors concluded, "[M]ost cases of pediatric Pb [lead] poisoning occur in an area of high soil Pb values." Fairey & Gray, Soil Lead and Pediatric Lead Poisoning in Charleston, S. C., J.S.C. MED. ASSN 79 (March 1970), JA 482, 485. Petitioners distort the purpose of this study and then attack the resultant straw man. As petitioners correctly note, Nalco Supp. Br. at 43-44; PPG/duPont Supp. Br. at 43; Ethyl Supp. Br. at 50, the high lead concentrations in the area studied were not thought to be a direct product of automotive exhausts. *See* JA 484, 485. Since the study is only cited to show that children are likely to eat lead-contaminated dust, however, petitioners' charge proves little. Third Health Document at VI-4, JA 114. On the other hand, petitioners fail to note that the study did implicate automotive exhausts to some extent:

> Neither pesticides nor automobile exhausts account for the high Pb [lead] levels in Charleston, though undoubtedly they add to the contamination.

JA 484.

Petitioners attempt to rebut the Charleston findings, and those of the El Paso study, *see* note 5 *infra* and accompanying text, by relying on apparently contradictory data from England showing inconsequential increases in children's blood lead levels despite significant changes in soil lead levels. PPG/duPont Supp. Br. at 43-44; Ethyl Br. at 42, *citing* Barltrop & Strehlow, "The Significance of High Soil Lead Concentrations for Childhood Lead Burdens," presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C. (Oct. Administrator pointed to various possible differences between 1-2, 1973), JA 415. *But see* EPA Supp. Br. at 57 n.51. The

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work in the smelter community of El Paso, Texas shows that elevated blood leads among children decrease with distance from the smelter.[5] This gives substantial support to the claim that children can ingest lead-contaminated dust in significant amounts. And a major epidemiological study in Newark[6] supports this inference with evidence relating directly to automobile lead. It found children living within 100 feet of heavily traveled

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the American and English data that might account for the inconsistency. Third Health Document at VI-5, JA 115. We shall defer to his judgment that the American data are preferable.

[5] Within one mile of the smelter 35.2% of the children tested had blood lead levels of 40 ug or greater; beyond that the percentage dropped to around 10. Epidemiological Studies of Human and Environmental Lead Pollution: El Paso, Texas (unpublished 1972), JA 468 (Table 2). On the basis of this data the chairman of the NAS Panel concluded:

> [T]he Smeltertown [El Paso] study alone lends a high degree of credibility to the hypothesis that very young children will, in fact, ingest toxicologically significant amounts of dust and dirt when it contains lead at the level of 0.1 percent and up.

Letter from Dr. Paul B. Hammond to Dr. Kenneth Bridbord, EPA, March 9, 1973, JA 2417. While petitioners cited an apparently contradictory statement from Dr. Hammond, JA 2611, he has not repudiated the observation quoted above.

[6] Margulis *et al.*, "Residential Location, Ambient Air Lead Pollution and Childhood Lead Poisoning," — ARCH. ENV. HEALTH — (in press at time record was assembled), JA 626. Petitioners suggest that something is wrong with the Newark data because preliminary results did not reach the same conclusion. Nalco Supp. Br. at 42-43; PPG/duPont Supp. Br. at 40-41. Preliminary calculations on data points only above lead levels of 40 ug produced positive, but not significant, results, so the data field was expanded to include all the evidence whereby the results suggested below were obtained. We see nothing wrong with such refinement of experimental data. *See also* pp. 104-105 n.112 *supra*.

roadways had significantly higher blood lead levels than those living beyond that distance. When only children living near highways were considered, the study showed a direct relationship between blood lead level and traffic density; the more heavily traveled the roadway, the higher the blood lead level.[7] The plain thrust of all these studies is that the Administrator's hypothesis is well founded, that children do ingest toxicologically significant amounts of lead dustfall from automobile emissions.

Petitioners attack these studies for various reasons. Primarily, they argue that too many variables were uncontrolled and that the Administrator cannot properly extrapolate data from lead smelter communities to urban areas in general. We have examined these objections and find them to be without merit. The variables that were uncontrolled were uncontrollable and/or were ade-

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[7] Over 5,000 children were studied. Of those living within 100 feet of major highways, 49.3% had blood lead levels of 40-49 ug and 8.1% had levels of 60 ug or more; of children living between 100 and 200 feet from the highways, the respective percentages were 24.2 and 3.7. Margulis *et al.*, *supra* note 6, at Table 2, JA 639. Dividing these children into two groups, one containing children living near highways bearing an average weekday traffic density of less than 24,000 vehicles, the other containing children living near highways bearing more than 24,000 vehicles daily, the researchers found 51.3% of the latter group had blood lead levels of 40-59 ug, and 10.8% had levels greater than 60 ug; in the former group, however, the respective percentages were only 3.6 and 5.1.

Undoubtedly, respiration of airborne lead emissions contributed to the elevated blood lead levels, but the fact that a far greater percentage of these children had elevated blood lead than comparable adults, *see* the Daines study discussed at pp. A-11 to A-12 *supra*, suggests that ingestion of lead dustfall significantly supplemented any respiratory intake.

quately accounted for by the Administrator.[8] The use of the lead smelter data, in context, was not improper. Animal toxicological studies show that lead-contaminated dust from smelters and from automobiles is comparably

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[8] In particular, petitioners fault the Newark study for failing to correlate the children's blood lead level with exposure to leaded paint as well as distance from the roadway. Nalco Supp. Br. at 43; PPG/duPont Supp. Br. at 41-42; Ethyl Supp. Br. at 51. These data were impossible to obtain; the Newark study took advantage of a vast data base accumulated by the New Jersey College of Medicine and Dentistry in its routine measurements of childhood exposure to lead. The data contained only blood lead levels and addresses of children, thus making the lead paint variable impossible retroactively to control or measure, JA 954. However, the Administrator recognized this limitation on the study, Third Health Document at VI-17, JA 127, and determined that it did not seriously undercut its validity. Of course, the results were "only" a statistical correlation; such are the results of all epidemiological research. But the Newark study presented a strong correlation, consistent with an existing theory that makes biological sense and with existing evidence. Such data are worthy of great respect, and may even be taken as causal proof. H. HILLEBOE & G. LARIMORE, PREVENTIVE MEDICINE 677-678, 687 (1959). We cannot say the Administrator's reliance on the Newark study was in error.

Petitioners also argue the El Paso data is useless since blood lead levels were elevated in adults as well, so that the high lead body burdens may have been due to inhalation rather than ingestion. Nalco Supp. Br. at 41-42. While this suggestion may undercut petitioners' argument that inhalation of airborne lead does not significantly affect the lead body burden, it does not undercut the Administrator's use of the study. While adult blood leads were indeed elevated, the Administrator noted that the frequency of elevated blood leads among young children was much higher, thus suggesting "a special exposure route for young children," *i.e.*, ingestion. Third Health Document at VI-7, JA 117. (Petitioners overstate by at least a factor of 10 the air lead concentrations in El Paso, *compare* Nalco Supp. Br. at 41 *with* JA 117, 469, 2344.)

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absorbed. Third Health Document at VI-5, 6, JA 115-116. Moreover, the studies were used to prove only that lead-contaminated dust is in fact ingested by children; the source of the contamination was irrelevant to this purpose.

We likewise reject the evidence affirmatively presented by petitioners to disprove the dustfall theory. Most of it only proves that leaded paint is the primary cause of lead poisoning in children, something the Administrator had repeatedly acknowledged.[9] Petitioners rely primarily on the Ter Haar study,[10] produced by an Ethyl scientist. That study was an attempt to measure the actual contributions of lead-based paint and lead dustfall in eight children suspected of having high lead body burdens. The project tested the children's feces for the presence of a lead isotope, lead-210, more prevalent in fallout dust than in leaded paint. Six of the eight children showed elevated stable lead concentrations in their feces, indicating elevated lead body burdens, but none of the children showed lead-210 concentrations higher than those in a control group of normal children. Because of this, the authors concluded that the children suspected of elevated lead body burdens did not ingest dust.

The Administrator criticized the study for failing to measure the children's exposure to lead-210 in their diet or in the air; exposure by either of these routes could

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[9] Ter Haar & Aronow, New Information on Lead in Dirt and Dust as Related to the Childhood Lead Problem, presented at the EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, N. C., Oct. 1, 1973, JA 917, 922 (Fig. 1); Fine *et al.*, *Pediatric Blood Lead Levels*, 221 J. A.M.A. 1475 (1972), JA 486; Conn & Anderson, *D.C. Mounts Unfunded Program of Screening for Lead Poisoning*, 86 H.S.M.H.A. HEALTH REPORTS 409 (1971), JA 460; statement of Henrietta Sachs (Nov. 5, 1972), JA 2444.

[10] Ter Haar & Aronow, *supra* note 9.

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have confounded the results. Third Health Document at VI-11, 12, JA 121-122. Moreover, while positive results would have shown conclusively that some children ingested lead through dust, these negative results show only that the six children who tested positive had not eaten lead dustfall. Without some reason to believe their exposure to dustfall was typical of all children, extrapolation of the results beyond the sample studied is unwarranted—and is not suggested by the authors.[11] We cannot say the Administrator was irrational in refusing to credit the Ter Haar study, particularly in light of the positive, contrary data on which he relied.

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[11] As the study concluded: "The results provide sound evidence that *these* children suspected of elevated lead body burden were not ingesting dust or air-suspended particulate." JA 918 (emphasis added).

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BAZELON, *C.J., with whom* MCGOWAN, *J. joins, concurring*: I concur in Judge Wright's opinion for the court,[1] and wish only to further elucidate certain matters.

I agree with the court's construction of the statute that the Administrator is called upon to make "essentially legislative policy judgments" in assessing risks to public health.[2] But I cannot agree that this automatically relieves the Administrator's decision from the "procedural. . . rigor proper for questions of fact."[3] Quite the contrary, this case strengthens my view that[4]

> . . . in cases of great technological complexity, the best way for courts to guard against unreasonable or erroneous administrative decisions is not for the judges themselves to scrutinize the technical merits of each decision. Rather, it is to establish a decision-making process that assures a reasoned decision that can be held up to the scrutiny of the scientific community and the public.

This record provides vivid demonstration of the dangers implicit in the contrary view, ably espoused by Judge Leventhal, which would have judges "steeping" themselves "in technical matters to determine whether the agency has exercised a reasoned discretion."[5] It is one

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[1] For convenience, citations to particular pages are in the form "Wright op. at ——."

[2] Wright op. at 51.

[3] *Id.* at 46.

[4] International Harvester Co. v. Ruckelshaus, 155 U.S.App. D.C. 411, 448, 478 F.2d 615, 652 (1973) (Bazelon, C.J., concurring).

[5] Portland Cement Ass'n v. Ruckelshaus, 158 U.S.App.D.C. 308, 335, 486 F.2d 375, 402 (1973), *cert. denied*, 417 U.S. 921 (1974) (Leventhal, J.), *citing* Greater Boston TV v. FCC,

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thing for judges to scrutinize FCC judgments concerning diversification of media ownership to determine if they are rational. But I doubt judges contribute much to improving the quality of the difficult decisions which must be made in highly technical areas when they take it upon themselves to decide, as did the panel in this case, that "in assessing the scientific and medical data the Administrator made clear errors of judgment." [6] The process of making a de novo evaluation of the scientific evidence inevitably invites judges of opposing views to make plausible-sounding, but simplistic, judgments of the relative weight to be afforded various pieces of technical data.[7]

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143 U.S.App.D.C. 383, 392, 444 F.2d 841, 850, *cert. denied*, 403 U.S. 923 (1971).

The *Greater Boston TV* case, from which Judge Leventhal draws this language, involved FCC non-renewal of a license in part because it was held by parties controlling a major newspaper in the area. As indicated in the text, such issues are much more amenable to judicial comprehension than the scientific judgments in a case such as the present.

While acknowledging that the general rules of administrative law might be modified, rather than imported wholesale, into scientific and technical areas, Judge Leventhal apparently concludes that encouraging judges to parse the evidence themselves is necessary if courts are to remain "fully vigilant to exercise rather than abdicate their supervisory role" in areas such as environmental law which touch fundamental interests in life and health. *See* Leventhal, *Environmental Decisionmaking and the Role of the Courts*, 122 U.PA.L.REV. 509, 511-12 (1974).

[6] Panel op. at 48 [quotation omitted]. *See also* Wilkey op. at 58.

[7] For example, Judge Wright states little weight is to be given the absence of studies documenting actual harm from lead in auto emissions with the observation, among several others, that ". . . lead exposure from the ambient air is pervasive, so that valid control groups cannot be found against

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It is true that, where, as here, a panel has reached the result of invalidating agency action by undue involvement in the uncertainties of the typical informal rulemaking record, the court *en banc* will be tempted to justify its affirmation of the agency by confronting the panel on its own terms. But this is a temptation which, if not resisted, will not only impose severe strains upon the energies and resources of the court but also compound the error of the panel in making legislative policy determinations alien to its true function. We would be wiser to heed the admonition of the Supreme Court that: "[e]xperience teaches . . . that the affording of procedural safeguards, which by their nature serve to illuminate the underlying facts, in itself often operates to prevent erroneous decisions on the merits from occurring." [*]

Because substantive review of mathematical and scientific evidence by technically illiterate judges is dangerously unreliable, I continue to believe we will do more to improve administrative decision-making by concen-

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which the effects of lead on our population can be measured." Wright op. at 49.

Similarly, Judge Wilkey, in his original panel opinion, discounts the value of a particular study with the observation: "Realistically, it is impossible to say that any definite scientific or medical conclusion can be drawn from the observation of one or two subjects." Panel op. at 51.

I do not know whether or not these observations are valid, although it was my impression that techniques had been devised which minimized these problems in certain cases. Be that as it may, these overt examples of homespun scientific aphorisms indicate that on more subtle, and less visible, matters of scientific judgment we judges are well beyond our institutional competency.

[*] Silver v. New York Stock Exchange, 373 U.S. 341, 366 (1963).

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trating our efforts on strengthening administrative procedures: [9]

> When administrators provide a framework for principled decision-making, the result will be to diminish the importance of judicial review by enhancing the integrity of the administrative process, and to improve the quality of judicial review in those cases where judicial review is sought.

It does not follow that courts may never properly find that an administrative decision in a scientific area is irrational. But I do believe that in highly technical areas, where our understanding of the import of the evidence is attenuated, our readiness to review evidentiary support for decisions must be correspondingly restrained.

As I read the court's opinion, it severely limits judicial weighing of the evidence by construing the Administrator's decision to be a matter of "legislative policy," and consequently not subject to review with the "substantive rigor proper for questions of fact." [10] Since this result would bar the panel's close analysis of the evidence, it satisfies my concerns.[11]

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An additional matter which emerges from this record deserves comment: namely, the failure of the record to

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[9] Environmental Defense Fund, Inc. v. Ruckelshaus, 142 U.S.App.D.C. 74, 88, 439 F.2d 584, 598 (1971) (Bazelon, C.J.).

[10] Wright op. at 46.

This construction of the proper scope of review makes unnecessary Judge Wright's exhaustive analysis of the scientific evidence, which is evidently undertaken to answer those who believe we must judge the technical data for ourselves.

[11] *See* International Harvester Co. v. Ruckelshaus, *supra* note 4; Environmental Defense Fund, Inc. v. Ruckelshaus, *supra* note 9.

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clearly disclose the procedural steps followed by EPA. As a result, an onerous, time-consuming burden was cast upon the court to reconstruct these steps by inference and surmise. It is not enough for an agency to prepare a record compiling all the evidence it relied upon for its action; it must also organize and digest it, so that a reviewing court is not forced to scour the four corners of the record to find that evidence for itself.[12] These principles apply with no less force to judicial review of agency procedures. In informal rule-making, the record should clearly disclose when each piece of new information is received and when and how it was made available for comment. If information is received too late for comment, the agency must at least clearly indicate how the substance of its consideration would be affected.

It is regrettable that EPA did not give the same care to clearly setting forth procedural matters for the record as it gave to substantive matters. It may well be that this court's 30-day order interfered with the opportunity to do so. Based on that possibility, and the court's own reconstruction of the procedural record (albeit at the expense of much judicial time and effort), I am persuaded that the petitioner's rights were not prejudiced. Ordinarily, however, I think a record which so burdens judicial review would require a remand for clarification.

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[12] *See, e.g.*, Washington Gas Light Co. v. Baker, 88 U.S.App. D.C. 115, 188 F.2d 11, *cert. denied*, 340 U.S. 952 (1950); Monrote v. Britton, 99 U.S.App.D.C. 128, 131, 237 F.2d 756 (1956); Williams v. Robinson, 139 U.S.App.D.C. 204, 208, 432 F.2d 637 (1970); Environmental Defense Fund, Inc. v. EPA, 150 U.S.App.D.C. 348, 465 F.2d 528 (1972); Citizens Ass'n of Georgetown, Inc. v. Zoning Comm. of D.C., 155 U.S. App.D.C. 233, 477 F.2d 402, 408 (1973).

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Statement of Circuit Judge LEVENTHAL:

I concur without reservation in the excellent opinion for the court.

I write an additional word only because of observations in the concurring opinion authored by Chief Judge Bazelon. I would not have thought they required airing today, since they in no way relate, so far as I can see, to the court's en banc opinion. But since they have been floated I propose to bring them to earth, though I can here present only the highlights of analysis.

What does and should a reviewing court do when it considers a challenge to technical administrative decision-making? In my view, the panel opinion in this case overstepped the bounds of proper judicial supervision in its willingness to substitute its own scientific judgments for that of the EPA. In an effort to refute that approach convincingly the panel dissent may have over-reacted and responded too much in kind. In a kind of sur-rebuttal against such overzealousness, Judge Bazelon has also over-reacted. His opinion—if I read it right—advocates engaging in no substantive review at all, whenever the substantive issues at stake involve technical matters that the judges involved consider beyond their individual technical competence.

If he is not saying that, if he agrees there must be some substantive review, then I am at a loss to discern its significance. Certainly it does not help those seeking enlightenment to recognize when the difference in degree of substantive review becomes a difference in kind.

Taking the opinion in its fair implication, as a signal to judges to abstain from any substantive review, it is my view that while giving up is the easier course, it is not legitimately open to us at present. In the case of legislative enactments, the sole responsibility of the courts

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is constitutional due process review. In the case of agency decision-making the courts have an additional responsibility set by Congress. Congress has been willing to delegate its legislative powers broadly—and courts have upheld such delegation [1]—because there is court review to assure that the agency exercises the delegated power within statutory limits, and that it fleshes out objectives within those limits by an administration that is not irrational or discriminatory. Nor is that envisioned judicial role ephemeral, as *Overton Park* [2] makes clear.

Our present system of review assumes judges will acquire whatever technical knowledge is necessary as background for decision of the legal questions. It may be that some judges are not initially equipped for this role, just as they may not be technically equipped initially to decide issues of obviousness and infringement in patent cases. If technical difficulties loom large, Congress may push to establish specialized courts. Thus far, it has proceeded on the assumption that we can both have the important values secured by generalist judges and rely on them to acquire whatever technical background is necessary.

The aim of the judges is not to exercise expertise or decide technical questions, but simply to gain sufficient background orientation. Our obligation is not to be jettisoned because our initial technical understanding may be meagre when compared to our initial grasp of

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[1] Amalgamated Meat Cutters & Butcher Workmen v. Connally, 337 F. Supp. 737 (D.D.C., 1971) (3-judge court).

[2] 401 U.S. 402 (1971). Citizens to Preserve Overton Park v. Volpe requires the reviewing court to scrutinize the facts and consider whether the agency decision was "based on a consideration of the relevant factors" in the context of non-formalized, discretionary executive decisionmaking. A fortiori, at least that rigor of review should apply to more formal decisionmaking processes like informal rulemaking.

FCC or freedom of speech questions. When called upon to make de novo decisions, individual judges have had to acquire the learning pertinent to complex technical questions in such fields as economics, science, technology and psychology. Our role is not as demanding when we are engaged in review of agency decisions, where we exercise restraint, and affirm even if we would have decided otherwise so long as the agency's decisionmaking is not irrational or discriminatory.

The substantive review of administrative action is modest, but it cannot be carried out in a vacuum of understanding. Better no judicial review at all than a charade that gives the imprimatur without the substance of judicial confirmation that the agency is not acting unreasonably. Once the presumption of regularity in agency action [3] is challenged with a factual submission, and even to determine whether such a challenge has been made, the agency's record and reasoning has to be looked at. If there is some factual support for the challenge, there must be either evidence or judicial notice available explicating the agency's result, or a remand to supply the gap.[4]

Mistakes may mar the exercise of any judicial function. While in this case the panel made such a mistake, it did not stem from judicial incompetence to deal with technical issues, but from confusion about the proper stance for substantive review of agency action in an area where the state of current knowledge does not

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[3] Pacific States Box and Basket Co. v. White, 296 U.S. 176 (1935).

[4] Portland Cement Ass'n v. Ruckelshaus, 158 U.S.App.D.C. 308, 486 F.2d 375 (1973). It should be noted that the court remanded for further proceedings. It refused to vacate and set aside the agency's action, not withstanding motions filed for that specific purpose. This was made a ground for seeking certiorari. Certiorari was denied, 417 U.S. 921 (1974).

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generate customary definitiveness and certainty. In other cases the court has dealt ably with these problems, without either abandoning substantive review or ousting the agency's action for lack of factual underpinning.[5]

On issues of substantive review, on conformance to statutory standards and requirements of rationality, the judges must act with restraint. Restraint, yes, abdication, no.

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[5] *See e.g.*, Judge Wright's opinion in Amoco Oil Co. v. EPA, 163 U.S.App.D.C. 162, 501 F.2d 722 (1974); Judge McGowan's opinion in Industrial Union Dept. v. Hodgson, 162 U.S.App.D.C. 331, 499 F.2d 467 (1974).

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MACKINNON, *Circuit Judge*, dissenting: This complex and lengthy lawsuit was foreordained when, on October 29, 1973, a panel of this court directed the Administrator of the Environmental Protection Agency to reach a final decision *within 30 days*[1] on the need for and specific content of regulations on the lead content of leaded gasoline. Although the proposed rulemaking had then been in progress for nearly three years, it was patently unrealistic to believe that the agency could sift through its accumulated data, afford the public and other agencies an opportunity to review any evidence contributed since the end of the last comment period on March 11, 1973, reach a proper decision based on all the evidence and draft the complicated regulations within the required 30 days. Given the time constraints thus imposed upon the agency, it was impossible for it to comply with the notice and comment requirements of the Administrative Procedure Act,[2] and as Judge Wilkey

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[1] In an unreported order, this court directed the EPA to reach a final decision on the matter pending before it and to notify the court of such decision by November 27, 1973. Natural Resources Defense Council v. EPA, No. 72-2233 (D.C. Cir., Oct. 29, 1973).

[2] 5 U.S.C. § 553 (1970) provides:

§ 553. Rule making.

* * * *

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the ruling making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substan-

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points out they were not complied with.[3] The result of thus forcing a hasty decision from the agency on a highly complicated matter that was still under study is the flawed regulations which we now review.

I therefore join in Part I of the dissent. Unlike Judge Wilkey, however, I would specifically remand this record back to the EPA with instructions to reconsider the regulations in light of whatever criticism is received after a suitable notice-and-comment period. The agency should be cautioned to proceed to a decision as soon as possible under the circumstances, and this court would retain jurisdiction to order further expedition of the matter on petition if a decision was not reached by the agency within a reasonable period. I would set no specific deadline for agency action, however.

If the case were to be remanded to the EPA for compliance with the Administrative Procedure Act, the Administrator should also be directed to review the evidentiary support and the rationale for his decision. I agree that section 211(c)(1)(A) of the Clean Air Act[4] embodies strong precautionary powers, but I do not believe that it confers upon the Administrator the extreme powers to issue regulations that the majority

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tive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause and published with the rule.

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[3] *See* Part I-C of dissenting opinion.

[4] 42 U.S.C. § 1857f-6c(c)(1)(A) (1970).

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opinion interprets the statute to allow, *e.g.*, on a "non-existent data base . . . ." (Majority Opinion at 47). In my view the court's opinion in a number of respects exaggerates the Administrator's ability to act in the policy field without an underlying factual basis. Therefore, my general position on the powers of the Administrator lies between those expressed by the majority and the dissent. The "will endanger" standard of the Act is unquestionably a broad grant of authority, but to my mind it does require some showing of an actual danger—now or in the future—that has a rational, demonstrable basis in fact. Thus I do not agree that Congress intended to vest the Administrator with authority to act on a speculative basis to the extent the court would allow. In fact, I believe the court even overstates the authority necessary to uphold the Administrator's decision in this case. While I do not find that the evidence at this time meets the required standard, or that the Administrator has adequately supported his hypotheses, it is entirely possible on remand that the Administrator can produce a record adequate to justify his proposed regulations. Judge Wilkey perceptively examines many of the deficiencies in the Administrator's action in Part IV of his opinion. Upon a remand, the Administrator could do much to clarify the grounds upon which he bases his decision that the "will endanger" standard has been met.

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WILKEY, *Circuit Judge*, with whom joined *Circuit Judges* TAMM, and ROBB, dissenting:* We are called upon in these cases, consolidated for purposes of argument and decision, to review regulations promul-

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* OUTLINE OF OPINION

I. The Three-Year History of EPA's Efforts to Devise Acceptable Regulations (P. 4)

A. The Regulations and Supporting Health Documents (P. 4)

B. Adverse Nature of Government Expert Scientific Comment (P. 6)

C. The Opportunity for Informed Public Comment on the Third Health Document (P. 17)

1. The extent to which the Administrator relied upon new scientific data, appearing as EPA sponsored for the first time in the Third Health Document, as the basis for the final regulations. (P. 19)

2. The extent to which interested private parties, some of whom are petitioners here, were given or acquired actual notice of the existence of the scientific studies, were given notice as to which studies were to be relied upon by the Administrator in the Third Health Document, and commented thereon prior to the issuance of the Third Health Document itself. (P. 26)

II. The Legal Standard (P. 50)

A. The Statute—Its Interpretation (P. 50)

B. Threshold Factual Determination Required (P. 55)

III. Scope of Review (P. 57)

IV. The Evidence (P. 64)

A. This Court's Task (P. 64)

B. "A small but significant portion of the urban adult population . . . [is] over-exposed to lead." (P. 66)

1. The 40 ug Demarcation (P. 66)

2. Over-Exposure in the General Adult Population (P. 68)

[Continued]

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gated by the Environmental Protection Agency (EPA) pursuant to section 211(c)(1)(A) of the Clean Air Act.[1] The regulations provide for the phased reduction of the lead content of motor vehicle gasoline. By 1979 the regulations will permit refiners to manufacture gasoline which has an average lead content of no greater than 0.5 grams of lead per gallon.

In these cases EPA is acting under authority of section 211(c)(1)(A) of the Clean Air Act which permits EPA's Administrator to prohibit, control, or regulate a fuel or fuel additive if "the emission products of such fuel or fuel additive *will endanger the public health or welfare. . . .*" EPA's authority to promulgate these regulations must be distinguished from EPA's authority and action reviewed in this court's opinion in *Amoco Oil Co. v. EPA.*[2] In *Amoco* we had before us regulations

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* [Continued]

C. "[A]bsorption of air lead does contribute to total lead exposure and when added to lead from other sources . . . results in total exposure that is excessive." (P. 74)

D. The Contribution of Auto Lead Emissions to Blood Levels in Children—The Speculative Nature of EPA's Determination (P. 78)

V. Conclusion (P. 85)

Appendix (A-1)

[1] 42 U.S.C. § 1857f—6c(c)(1)(A) (1970).

[2] 163 U.S. App. D.C. 162, 501 F.2d 722 (1974). In the *Amoco* catalytic converter case we were dealing entirely with *un*leaded gasoline and the necessity for unleaded gasoline to be used to prevent destruction of the platinum catalytic converter. The Congress and EPA directed unleaded gasoline to be used, not because it had found that leaded gasoline in any quantity was dangerous to human health, but because it had been scientifically established that leaded gasoline would destroy essential elements of the catalytic converter in a very few thousand miles of use. Now this court is concerned with the possible impact of leaded gasoline on human health. This is a matter decided by neither EPA nor this

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which prohibited use of leaded gasoline in automobiles fitted with the catalytic converter for controlling exhaust emissions and required retail marketing of at least one grade of unleaded gasoline for the use of such automobiles.[3] Those regulations were issued under the authority of section 211(c)(1)(B) of the Clean Air Act which permits regulation, control, or prohibition of a fuel or fuel additive ". . . if emission products of such fuel or fuel additive will impair to a significant degree the performance of any emission control device or system which is in general use, or which the Administrator finds has been developed to a point where in a reasonable time it would be in general use. . . ."[4]

The petitioners challenge the regulations on two basic grounds. They contend the Administrator incorrectly interpreted section 211(c)(1)(A) and as a result used an improper legal standard in making the determinations upon which the regulations are based. More importantly, they also contend that the evidence in no way supports

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court in *Amoco*, nor was it decided by Congress when it enacted the legislation.

Unlike the basic facts in *Amoco*, we have here a situation in which leaded gasoline must necessarily be used in all pre-1975 cars and leaded gasoline may very well be used in many new cars manufactured without the platinum catalytic converter. Some of the parties before us have argued strenuously that the universality of use of the catalytic converter is by no means as certain today as when EPA promulgated its regulation. Other engineering devices to avoid the air pollution of the hydrocarbons, *i.e.*, PNA carcinogenic poisons, may come on the market, and the number of new cars using leaded gasoline increase. Be that as it may, the catalytic converter is a device to take out the PNA carcinogenic elements from gasoline; it is not in any way a device to take out lead.

[3] Those regulations appear at 38 FED. REG. 1254 (10 Jan. 1973) and are reproduced in full as an Appendix to the *Amoco* opinion.

[4] 42 U.S.C. § 1857f—6c(c)(1)(B) (1970).

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EPA's conclusion that the public health is or will be endangered, and that the case against auto lead emissions is a speculative and inconclusive one at best.[5] On reargument the dissenting judges conclude that the disagreement with regard to the legal standard reduces itself to semantics, and while the Administrator did not couch his principal determinations in the language of the statute, the language that he did use, properly interpreted in accordance with the statute, did provide a sufficient standard for his determinations. Taking the Administrator's own phrasing of his statutory authority, we are convinced that the paucity of scientific evidence pointing to any firm conclusion, the gaps in the logic supporting the Administrator's analysis, aggravated by the faulty procedure behind the promulgation of the regulations and the Third Health Document, render the issuance of the challenged regulations arbitrary and capricious and procedurally infirm.[6]

I. The Three-Year History of EPA's Efforts to Devise Acceptable Regulations

A. *The Regulations and Supporting Health Documents*

The regulations we are reviewing lessen the use of certain lead compounds, known as lead antiknocks, in motor vehicle gasoline.[7] These compounds control a phenomenon known as knock—the detonation of gasoline in the cylinder prior to maximum compression. Knocking places a limitation on the efficiency and economy of the internal combustion engine because maximum power is only obtained when the explosion in the cylinder occurs at that point when fuel and air are most compressed.

[5] Petitioners also raise other objections to the regulations which we do not need to reach. *See* note 186 *infra*.

[6] 5 U.S.C. §§ 706(2)(A) & (D) (1970).

[7] The regulations appear at 40 C.F.R. § 80 (1975).

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Lead antiknock compounds raise a fuel's resistance to knock (known as the octane of the fuel), thus permitting higher compression engines, which in turn are more efficient and economical in their use of fuel. The refiners claim that to achieve the same antiknock qualities without lead additives would require greater amounts of scarce crude oil. In addition, they claim that lead additives provide them with the flexibility to produce gasoline with differing antiknock qualities (differing octane ratings) with the minimum of refining and processing equipment.

The final regulations were accompanied by a detailed health position paper, entitled "EPA's Position on the Health Implications of Airborne Lead" [hereinafter referred to as the Third Health Document].[8] The document was intended to be an authoritative examination of the ". . . pertinent evidence upon which a decision could be made as to whether or not there is a health justification to regulate lead in gasoline."[9] We shall refer extensively to this document in reviewing the evidence in Part IV below.

The Preamble to the Regulations contains an extended discussion of EPA's health concern. It focuses separately upon adults and children. While conceding that the available evidence does not show that lead in auto emissions alone adversely affects the health of either adults or children, EPA argues that auto lead emissions make a significant cumulative contribution to human lead exposure. EPA declares that it would be "prudent" to limit this source of lead exposure, because it is a component of overall lead exposure susceptible to human control. Much of the discussion in the Preamble to the Regulations relates to whether airborne lead from auto emissions ac-

[8] Doc. 7, Appendix to the Briefs [hereinafter App.] at 27 (28 Nov. 1973).

[9] *Id.* at 30.

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tually does get into the human body to a significant degree. (That portion of the Preamble that refers to EPA's health concern is reproduced as an appendix to this opinion.) EPA contends that airborne lead is respired by persons in certain occupational groups and contributes to their high blood lead levels. It is also contended that young children ingest dust and dirt containing lead from auto emissions which contributes to excessive blood lead levels among the young. Petitioners take issue with both forks of EPA's argument, pointing out that the evidence is inconclusive on both issues.

B. *Adverse Nature of Government Expert Scientific Comment*

The present section 211 was added to the Clean Air Act on 31 December 1970.[10] Section 211(c)(1) authorizes the EPA Administrator to

> control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive for use in a motor vehicle or motor vehicle engine (A) if any emission products of such fuel or fuel additive will endanger the public health or welfare . . . .[11]

Within a month of the enactment of the Clean Air Act EPA issued an advance notice of proposed rulemaking.[12]

Almost three years passed before the final regulations were promulgated. This extended gestation period has significance in itself. Implicit in the administrative record generated by this three-year delay is the recognition by EPA that available scientific data did not provide

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[10] Clean Air Act Amendments of 1970, § 9(a), Pub. L. 91-604 (31 Dec. 1970).

[11] 42 U.S.C. § 1857f—6(c)(1) (1970).

[12] 36 FED. REG. 1486 (30 Jan. 1971).

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a clear and certain basis for reaching the statutorily mandated conclusion, *i.e.*, that a "fuel additive will endanger the public health or welfare."

What the gestation period of these regulations would have been without the intervention of this court, we will never know, for the decision to issue the regulations was precipitated by the third in a series of orders of this court in *Natural Resources Defense Council v. EPA* [13] on 29 October 1973, directing the agency to reach a final decision within thirty days. Out came the final regulations on 28 November, accompanied by the Third Health Document as the supporting scientific rationale for the regulations. The history of the regulations is really the history of the EPA Health Documents, a history of EPA's effort to discover somewhere, somehow, a scientific rationale which would withstand the unanimous criticism of the remainder of the government scientific community.

In February 1972, over a year after the prompt advance notice, the Administrator issued a notice of proposed rulemaking under section 211(c)(1)(A).[14] In the notice the Administrator stated the following conclusion: "that airborne lead levels exceeding two milligrams per cubic meter, averaged over a period of three months or longer, are associated with a sufficient risk of adverse physiologic effects to constitute endangerment of public health." [15] EPA's first health document, entitled "Health Hazards of Lead," was issued contemporaneously. Subsequently, an additional paper entitled "Atmospheric

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[13] No. 72-2233 (D.C. Cir., 29 Oct. 1973) (Wright & McGowan, JJ.)

[14] 37 FED. REG. 3882 (23 Feb. 1972), App. at 23.

[15] *Id.*

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Lead and Public Health" was issued by EPA to bolster further EPA's conclusion.[16]

In the ensuing year EPA received a great deal of adverse comment as to its health position, including critical comment from every other department of the Government asked to comment thereon. We regard this of considerable significance, as each of these departments has its own independent scientific staff, and presumably is in that group of "independent" experts to which EPA itself stated (rightly or wrongly) that it would give more credence than to either industry scientists or environmental crusaders.[17] Dr. Edward E. David, Jr., Director of the White House Office of Science and Technology, wrote:

> . . . OST has reviewed the medical evidence that supposedly supports the EPA Administrator's desire to reduce lead content of gasoline. OST finds the Administrator's position in this regard unsupported by the evidence.
>
> . . .
>
> With respect to the medical evidence there is no correlation between airborne lead and lead levels in

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[16] Doc. 12, App. at 276 (11 April 1972).

[17] Our colleagues chide us for characterizing the views of government agencies besides EPA as "independent" scientific appraisals. Yet the majority is willing to accept a view from HEW they deem somewhat favorable to their position because HEW "shares with EPA responsibility for and scientific expertise in the areas of public and environmental health. . . ." Court's opinion at 96 n.98. We submit that other departments of the Government (*e.g.*, the Departments of Interior, Commerce, and Transportation) share this same responsibility. When Congress created EPA it did not intend for that agency to become the Government's sole spokesman on environmental concerns.

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> blood for the range of airborne lead levels encountered in rural or urban communities. . . .[18]

In "Airborne Lead in Perspective," the National Academy of Science (NAS) made a thorough study of the scientific literature as to lead in the air and its biological effects [hereinafter referred to as the NAS Report]. After preliminary comparison of the NAS Report and EPA's health grounds, the Under Secretary of the Interior, M. J. Pecora, gave his evaluation:

> After examining the National Research Council report and that of the background information of EPA, it seems that EPA's conclusions are strongly oriented toward a one-sided view of the report's findings. In general, the Research Council indicates there is no basis for restriction of lead in gasoline from a health standpoint.[19]

The Department of Commerce commented:

> It therefore appears that EPA's position that any amount of airborne lead constitutes an endangerment of public health is largely conjectural and not

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[18] Memorandum from Dr. Edward E. David, Jr., Office of Science and Technology, to Donald E. Crabill, Chief, Natural Resources Programs Division, Office of Management and Budget, 1 Nov. 1972, App. at 2471.

[19] Letter from M.J. Pecora, Under Secretary of the Interior, to George P. Schultz, Director, Office of Management and Budget, 14 Feb. 1972, App. at 2501.

In the preface to its report the NAS panel stated that it had "decided to consider biologic effects of lead not necessarily attributable directly to atmospheric sources and not necessarily at levels of exposure as low or as prolonged as those related to general ambient air. Such consideration was necessary because lead attributable to emission and dispersion into general ambient air has no known harmful effects." NAS Report, Doc. 14, App. at 314.

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adequately premised on available scientific or medical information.[20]

Perhaps the most biting comment came in a letter from Dr. Merlin K. DuVal, Assistant Secretary for Health, Department of Health, Education and Welfare:

> *The decision having been made on grounds other than those having to do with hazard to the public health*, your staff now wish to explore with us the question of whether or not hazard to the public health could be invoked as a reason for accelerating the implementation date of the primary decision. It was our firm view that there is no firm evidence, at this time, that lead poisoning in humans could be traced *per se* to the presence of lead in gasoline, indeed, if there were, this would have constituted justification for the elimination of lead as an additive in the first instance.[21]

As a result EPA was forced back to basics, asking for public comment on virtually every conclusion it had reached as to lead in the air and its relation to man.[22]

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[20] Letter from W. N. Letson, General Counsel, Department of Commerce, to Casper W. Weinberger, Director, Office of Management and Budget, 2 Nov. 1972, App. at 2464.

[21] Letter from Merlin K. DuVal, M.D., Assistant Secretary of Health (HEW), 17 Nov. 1972, App. at 2481.

[22] The Environmental Protection Agency is attempting to gather additional health effects information by asking various members of the medical and scientific community to respond to the following questions. All other interested parties are also invited to address these questions:

(1) In the light of any criticisms you may have of the Goldsmith Hexter approach and the Environmental Protection Agency's use of a regression equation based upon it (see Figure 3-3 of "Airborne Lead in Perspective." National Academy of Sciences, 1972, and Table 7 of the "Health Hazards of Lead," Environmental Protection

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On 4 January 1973 a new notice of proposed rulemaking was issued, in which EPA repudiated its earlier conclusions and reached the following weakened appraisal:

Agency, revised April 11, 1972, which was corrected in "Corrections and Additions to Health Hazards of Lead," April 27, 1972), what are the permissible uses and limitations in its application for obtaining reasonable estimates of blood lead levels as a function of air lead exposures?

(2) How accurate a reflection is blood lead of lead body burden? What is the effect of elevated blood leads upon lead body burden? Can small increments in blood lead be expected to result in a significant lead body burden elevation? From a public health point of view, is it permissible to allow slight increases in lead body burdens among the general population when this increment can be prevented? Can the pool of body lead stored in the bone be viewed as totally "physiologically inert"? It is known that chelation therapy of children with elevated blood leads can result in acute clinical symptoms of lead poisoning as a result of mobilizing lead from bone. Is there any evidence that subtle metabolic changes could also mobilize this lead pool under other conditions?

(3) The Environmental Protection Agency has relied upon the National Academy of Sciences (NAS) Report (Appendix C, p. 249, footnote "a") for estimates of daily respired air by an average adult in its own calculations in Table 7 of the "Health Hazards" paper. How accurate are these estimates of pulmonary physiology (a) that an adult male breathes 23 cubic meters of air per day, (b) that 30 percent of respired lead particles will be retained, and (c) that nearly 100 percent of retained lead particles will be absorbed? Is there additional evidence available in this area besides that which is cited in the NAS Report?

(4) What is an appropriate safety factor for extrapolating industrial threshold limit values (TLV) to the general population? Should such an extrapolation to the general population even be permitted? The proposed TLV for lead is due to be revised to 150 μg./m.^{3} for a 40-

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Though none of the above findings viewed individually and in the context of possible experimental error can be taken as conclusive evidence that airborne lead by itself is a current public health prob-

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hour week. On a weekly basis, this corresponds to breathing air continually at between 35-40 μg./m.^{3} of lead. If TLV's can be extrapolated to the general population, what would be an appropriate safety factor for this purpose so that all groups, including those most suscepible to lead will be protected?

(5) In regard to the dustfall lead theory (p. 139 of the NAS Report): How much of a hazard is dustfall lead to children prone to pica? The Environmental Protection Agency's calculations indicate that continued ingestion of even small amounts of lead contaminated dusts and dirt containing as much as 0.25-0.35 percent lead could theoretically result in dangerously elevated blood leads among children, or could contribute significantly to additional unnecessary lead burdens in children with other known lead exposures (such as lead paint). Will the Environmental Protection Agency's proposed 60-65 percent of reduction of leaded auto emissions significantly reduce the risk of this potential contamination?

(6) Although lead paint has traditionally been considered the prime causal factor in childhood lead poisoning, how effective would reductions in other known environmental sources of lead exposure (such as dustfall) be in helping to reduce the risk of undue lead exposure among children also exposed to peeling lead paint? How clear is it that all lead poisoning in children is, in fact, caused only by lead paint? Since many years are required to solve the lead paint problem, would the risk of undue lead absorption and possible lead poisoning not be reduced by also decreasing airborne lead and consequently lead in dust?

(7) What the consequence upon the environment in general of allowing large quantities of lead to be expelled into the atmosphere from motor vehicle exhausts? Does this environmental contamination pose any direct or indirect threat to man?

37 FED. REG. 11786, 11787 (14 June 1972), App. at 21.

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> lem, considered together, they do suggest that airborne lead is contributing to excessive total lead exposures among the general urban population. In light of this evidence, the Administrator has concluded that it would be prudent to reduce preventable lead exposures from automobile emitted "airborne" lead to the fullest extent possible.[23]

This latest EPA position was supported by a Second Health Document.[24]

Despite these changes in EPA's position, criticism from other governmental agencies continued. For example, Dr. Charles H. Powell, Assistant Director of the National Institute for Occupational Safety and Health of the United States Public Health Service, evaluated the reproposed regulations and the Second Health Document, as follows:

> We have not been persuaded, however. that reduction in environmental lead by its reduction in gasoline will result in a significant improvement in the health of the public. This statement is based on our review of the problem and discussions with responsible scientists in the Health Services and Mental Health Administration (NIOSH and BCEM) and the Food and Drug Administration.
>
> This position has been reconsidered by a review of the report on health effects of airborne lead submitted with your letter. The report is often speculative and is based in significant part on unpublished information, which we have not been able to review. We have been able to review some of the abstracts of the October 1972 meeting in Amsterdam, but this has not been sufficient to allow evaluation of the content of the papers.

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[23] 38 FED. REG. 1258, 1259 (10 Jan. 1973), App. at 16.

[24] Doc. 9, App. at 158 (29 Nov. 1972).

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> A specific point that has been commented on in previous drafts of this paper is the description of lead absorption in greater than normal amounts, as reflected by higher than normal blood lead levels, as asymptomatic lead poisoning. In the present version, this description is attributed to unnamed clinicians and health departments, whose knowledge, reputation, and expertise cannot be evaluated. It invites unfavorable inferences.[25]

Acting Secretary of the Interior John C. Whitaker stated, "After reviewing the reproposed regulations, we see no reason to change from our position as detailed in our enclosed analysis. . . ." [26]

Secretary Elliot L. Richardson of Health, Education, and Welfare (HEW), in a letter to Senator Tunney, took issue with EPA's revised health justification for the regulations:

> Our view is:
>
> (a) there is no firm evidence at this time that lead derived from combusted gasoline is harmful to the health of the general public, though it may, under certain circumstances, contribute to the total body burden of lead and may, as a consequence, reduce somewhat the physiologic reserve against lead poisoning from other sources . . . .[27]

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[25] Letter from D. Charles H. Powell to Dr. Kenneth Bridbord, Acting Chief, Health Effects Branch, Office to Research and Monitoring, EPA, 2 Mar. 1973, App. at 2477.

[26] Letter from Acting Secretary John C. Whitaker to Hon. William D. Ruckelshaus, Administrator of EPA, 26 Feb. 1973, App. at 2494.

[27] Letter from Elliot L. Richardson, Secretary of Health, Education, and Welfare to Senator John V. Tunney, 29 Jan. 1973, App. at 2479. Admittedly, HEW did soften its position on EPA's regulations when Richardson's successor, Caspar Weinberger, became Secretary of HEW. In a letter

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At this point it is perhaps appropriate to point out that we are not substituting our judgment for that of the Administrator; as members of a reviewing court we are saying that his procedural process was faulty, and that on the data he had available to him any conclusion could be only speculative. We are not disputing a supposed expert's conclusions on his own ground, but it is readily apparent from the recital of the other government agency comments that we would have plenty of company in our judgment if we did. Our analysis of the flaws in

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to David Shoenbrod of Natural Resources Defense Council, Inc., Secretary Weinberger stated,

> A final Departmental position, summarizing [HEW's] technical comments, was submitted to EPA prior to the final rule making. The conclusions stated in the letter to EPA were substantially the same as those expressed in the letter to Senator Tunney [from Secretary Richardson. App. at 2479.] . . .
>
> The position of the Department on the removal of lead from gasoline is that it should be removed because it provides no known direct benefit for human health and *may* contribute to the body burden of lead, but this should not be done unless it is clear that the health consequences associated with the alternatives to lead in gasoline are indeed less hazardous.

Letter dated 7 Aug. 1973, App. at 2507 (emphasis in original). We do, not however, read Secretary Weinberger's comments as a repudiation of HEW's "*final* Departmental position" (emphasis added). Indeed, Secretary Weinberger appears to be quoting from Secretary Richardson's earlier letter when he uses the phrase "*may* contribute to the body burden of lead." (emphasis in original.) Additionally, Weinberger's other rationale for lead removal—that lead "provides no known direct benefit to human health"—clearly is not a sufficient basis for EPA's low lead regulations. Thus, we conclude that Weinberger's letter to NRDC *did not alter HEW's prior conclusion* that *"there is no firm evidence at this time that lead derived from combusted gasoline is harmful to the health of the general public."*

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the Administrator's logic finds powerful support in the unanimity of conclusion of the independent scientific minds concerned throughout the Government outside of EPA itself. For the collective scientific judgment in every department or agency of the Government commenting on the first two EPA Health Documents and proposed regulations is dead against the Administrator's conclusions—and he did not risk the same fate with the Third Health Document.[28]

On 28 November 1973 the final regulations here under review were promulgated after an order of this court directed the Administrator to reach a final decision on the matter within thirty days.[29] These final regulations

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[28] With reference to the majority's notes 53 and 77, the distinction between the position of the writer of this opinion and his position in *Environmental Defense Fund, Inc. v. EPA (Coahoma)*, 160 U.S. App. D.C. 123, 128, 489 F.2d 1247, 1252 (1973), is obvious. In *Coahoma* we had a mass of evidence, often conflicting, on which the Administrator and his aides as the experts were entitled to draw their conclusions. For a court to dispute those conclusions, when there was a mass of evidence to sustain them (or indeed possibly to sustain opposite conclusions), would be for the court to assume an expertise that is properly that of the Administrator. We did not do so, and we thus sustained the Administrator.

In the instant case, as members of a reviewing court we are saying that the Administrator's process was faulty, that the logic of his conclusion has great gaps in the chain, and that the evidence to support his conclusion is totally insufficient. "The agency must articulate a 'rational connection between the facts found and the choice made.'" *Bowman Transp. Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974). The agency's choice here is only a guess, not an expert judgment drawn from conflicting evidence. We are thus dealing here with procedure, logic, and substantiality of evidence, not attempting to dispute a supposed expert's conclusions from a mass of evidence.

[29] *Natural Resources Defense Council v. EPA*, No. 72-2233 (D.C. Cir., 28 Oct. 1973).

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were accompanied by the Third Health Document, whose subjection to public—or other government official—comments will be now explored.

C. *The Opportunity for Informed Public Comment on the Third Health Document*

The Administrative Procedure Act (APA) provides that the notice of rulemaking shall include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." [30] Notice was given at the outset of the three-year rulemaking period, and also early in 1973 when in response to comments EPA reproposed the regulations with slight changes. In the fall of 1973, when the change in the regulations from leaded pool averaging to total pool averaging was about to be made, EPA notified interested parties and comments were received on this. As will appear from our detailed analysis later, nearly all of the comment received in October-November 1973, so stressed by the majority opinion, related to the economic impact of the regulations and total pool averaging, not to the health issue involved on this appeal.

Pertinently, the APA also provides in section 553(c):

> After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall . . . ."

Pursuant to this statutory provision, ample opportunity was given interested private parties and government agencies to comment on the original proposed regulations, the regulations reproposed with slight modifica-

[30] 5 U.S.C. § 553(b)(3) (1970).

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tions, and the first two Health Documents. The last formal period of comment, on the Second Health Document and the reproposed regulations, closed 11 March 1973. It is for the subsequent period that the question arises as to whether the agency gave "interested persons an opportunity to participate in the rulemaking through the submission of written data, views, or arguments . . ."; more precisely, whether an opportunity was afforded to submit written data, views, or arguments specifically directed to the Third Health Document and the new studies EPA was preparing to embrace therein.

Three matters seem beyond dispute:

(1) The Third Health Document was issued simultaneously with the final regulations on 28 November 1973.

(2) No formal period of comment was announced on the Third Health Document, although a "draft Third Health Document" was apparently given at least a limited circulation on 19 October 1973.

(3) The independent scientific minds in the other government agencies, whose devastating critical comments on the first two Health Documents have been discussed above, made no comment on the Third Health Document.

It is highly significant that nowhere in the fourteen-page detailed discussion of the EPA procedures at the close of their opinion do our colleagues maintain that such independent government agency scientific comment was received by EPA, although our colleagues go to great lengths to establish notice in fact and comment by some of the private industry petitioners upon portions of the scientific studies which eventually made up the Third Health Document.

Two matters appear very much in dispute:

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(1) The extent to which the Administrator relied upon new scientific data, appearing as EPA sponsored for the first time in the Third Health Document, as the basis for the final regulations.

(2) The extent to which interested private parties, some of whom are petitioners here,

(a) were given or acquired actual notice of the existence of the scientific studies,

(b) were given notice as to which studies were to be relied upon by the Administrator in the Third Health Document, and

(c) commented thereon prior to the issuance of the Third Health Document itself.

We set forth the record facts on these two issues as briefly as is consistent with clarity and accuracy:

1. *The extent to which the Administrator relied upon new scientific data, appearing as EPA sponsored for the first time in the Third Health Document, as the basis for the final regulations.*

The Preamble to the Regulations (attached to this opinion) makes clear that when the Administrator decided, he relied materially upon studies which had not before been subjected to public criticism. In the Administrator's own words, "A discussion of the four major areas of criticism and a summary of the *significant new information received since the regulations were reproposed* are provided below."[31] In this Preamble, after the Administrator posed the central evidentiary question—Is there a correlation between air lead levels and blood lead levels?—he then reviewed the critical comment received by EPA on the studies it had been using to support the existence of a correlation, and then notably made no

[31] 38 FED. REG. 33735, App. at 3.

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attempt to defend the earlier studies. Instead, he "weighed against these criticisms [new] studies which have shown that airborne lead does contribute significantly to lead exposure in the general population." [32]

The Preamble then launches into a discussion of six studies relating to lead as a hazard to the general public —two pilot isotope studies, "[a]n unpublished study in Japan," "the Chamber studies," the Seven Cities study, and the Daines study. These were followed by several studies relied on for the Administrator's conclusions concerning children in urban areas—the Newark studies (two parts), and the Chicago, Philadelphia, and Rochester (N.Y.) studies.

(a) *Pilot Lead Isotope Studies*—In the Third Health Document EPA relies on two pilot lead isotope studies by the same authors—Rabinowitz, Wetherill, and Kopple. The first of these studies is an unpublished paper presented to a scientific conference at Raleigh, North Carolina, on 1-2 October 1973.[33] The preliminary results of this study were reported to EPA in a letter dated 28 August 1972, which was filed and indexed with the public comments at that time.[34] This letter, however, empha-

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[32] *Id.*

[33] Doc. 113, App. at 678.

[34] Doc. 875. *See also* EPA letter of 2 Oct. 1975. It is interesting to note the comment of an EPA attorney explaining why he did not advise the court of this letter's existence at an earlier date: "The letter was filed and indexed with the public comments, under 'California University' and I overlooked it before." EPA letter of 2 Oct. 1975. If EPA had such difficulty locating this document, how can it be argued that this letter was "available" to the public in any meaningful sense? This is indicative of the extraordinary efforts to which the majority opinion is forced to resort in attempting to find compliance with required administrative procedures.

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sized the preliminary nature of the reported results,[35] and there is no indication that EPA received a more complete and final version of the study before its presentation at the October 1973 conference. After the conference, on 4 October 1973, abstracts of the paper were placed in EPA's public comment file and sent to Ethyl Corporation under an agreement resulting from a Freedom of Information Act (FOIA) suit brought by Ethyl.

The second pilot lead isotope study was published in the November 1973 issue of *Science* magazine.[36] An early draft of this study was sent to EPA by one of its authors on 5 May 1973.[37] The revised and final draft of this study was not received by EPA, nor sent to Ethyl under the FOIA agreement, nor placed in the public comment file until sometime after 6 August 1973.[38] Thus, the two pilot lead isotope studies, in the forms relied upon in the Third Health Document, did not reach Ethyl under the FOIA agreement or anyone else via EPA's public comment file until at least 4 October 1973 and 6 August 1973, respectively.

(b) *Unpublished Study in Japan*—Significantly, the cover page of this study bears the following inscription: "*Draft/Do Not Cite or Quote.*"[39] This unpublished study

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[35] Dr. George W. Wetherill, the author of the letter to EPA, cautioned,

> . . . We have by no means completed analysis of materials obtained in this study . . . . [M]ore accurate data will be forthcoming . . . . I expect that these results are not peculiar to the individual whom we have studied. Of course, this conclusion requires verification.

Doc. 875. *See generally* EPA letter of 2 Oct. 1975.

[36] Doc. 113, App. at 704.

[37] Doc. 470. *See also* EPA letter of 26 Sept. 1975.

[38] *See* EPA letter of 26 Sept. 1975.

[39] Doc. 462, App. at 1092.

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was transmitted to Ethyl under the FOIA agreement and placed in the public comment file on 22 July 1973,[40] but it is not even cited or referred to in the Third Health Document. Its absence from the Third Health Document is critical because the purpose of EPA's Health Documents was notice—notice of the particular items of evidence (*i.e.*, studies) on which EPA intended to base its regulations. Only with such notice would interested parties be able to make meaningful and effective comments.

(c) *The Chamber Studies*—The Chamber studies[41] were cited in the Second Health Document, but were only available at that time in preprint form. The Third Health Document relies upon the printed report which is dated May 1973.[42]

(d) *The Seven Cities Study*—The Preamble's discussion of blood lead levels of urban and suburban residents and between cities probably refers to both the Seven Cities study and the Daines study. The Preamble earlier had referred directly to the Seven Cities study as an example of previous EPA data which had been cited by other experts as contrary to EPA's own conclusions:

> For example, the Seven Cities Study did not show a close correlation between increase in blood lead levels and simultaneous increases in air lead exposures. Blood lead levels were lower among the New York City residents studied than the Philadelphia residents, despite the fact that air lead exposures among the New York residents were actually greater than those in Philadelphia.[43]

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[40] EPA letter of 26 Sept. 1975.

[41] Doc. 85, App. at 596.

[42] App. at 107 (reference 17).

[43] 38 FED. REG. 33735, App. at 3.

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Both the Preamble and the Third Health Document state that "EPA has reanalyzed the Seven Cities study and has found that air lead was a significant, though not the most influential factor affecting blood lead levels." [44] This "Additional Analyses of the Seven City Lead Study" bears a 15 March 1973 date.[45]

The majority opinion asserts that EPA made the re-analysis public at an EPA committee meeting on 26 February 1973—thirteen days before, instead of four days after, the close of the formal comment period on the Second Health Document (11 March 1973).[46] The majority also seems to attach great importance to the fact that "[r]epresentatives of Ethyl attended the meeting, prepared a transcript of it, including critical comments by some of those in attendance, and forwarded the transcript to the Administrator." [47] Of course, this EPA committee meeting with only one of the petitioners in this lawsuit present did not notify other interested parties (or, for that matter, even Ethyl) that EPA intended to rely on this re-analysis to support its regulations. Such a limited gesture adheres to neither the letter nor the spirit of the APA's notice provision.

(e) *The Daines Study*—The Daines study had been published in *Industrial Medicine* in October 1972. It and the Chamber studies represent the only studies mentioned in the Preamble to appear in equivalent form in both the Second and Third Health Documents.

(f) *The Newark Studies*—This study was done in *two* parts by the same investigators. After studying blood levels of children in various areas of Newark, the first

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[44] *Id.*; App. at 89.

[45] Doc. 228.

[46] Court's opinion at 105 & n.114.

[47] *Id.* at 105 n.114.

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paper of May 1973 was unable to relate elevated blood levels to traffic or traffic density, or to any other variable source. The investigators were with EPA in spirit, though, even if not with the facts, for they wistfully reported, "We only wish our results were more positive." [48]

Petitioners strongly attack the Newark study. They point out that in May 1973 "the investigators found no statistically significant correlation between blood lead levels and proximity to traffic or traffic density . . . ." [49] Yet in November 1973, by "increasing the amount of data in the study through the inclusion of another group of children with blood lead levels less than 40," the investigators suddenly were able to find the statistically significant correlaion that eluded them in May.[50] EPA concedes that it was only upon the submission of new data and reanalysis that the study was able to provide support for EPA's dirt and dust hypothesis by *November 1973;* however, EPA contends that "[p]etitioners make no argument why this additional data may not legitimately be included." [51] What EPA conveniently forgets is that the second paper was only in press *in November 1973, and had not even been published when the regulations were issued.* To our minds, if one pays any deference to primary principles of administrative procedure, this is a powerful argument against EPA's reliance on this data.

(g) *The Chicago, Philadelphia, and Rochester Studies* —In both the Preamble and in the Third Health Document itself heavy reliance is placed on the studies from Chicago, Philadelphia, and Rochester (N.Y.), as well as

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[48] Doc. 257, App. at 957.

[49] PPG/Du Pont Supplemental Brief at 40.

[50] *Id.* at 40-41.

[51] Brief for EPA in Nos. 73-2268 & 73-2269 at 32.

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the studies from Newark.[52] The results of the Chicago screening,[53] the Philadelphia study,[54] and one of the two Rochester studies [55] were first presented in papers at the October conference in Raleigh, North Carolina. The other Rochester study,[56] like the Newark study above, was in press at the time the regulations and the Third Health Document were promulgated by EPA.

According to the Third Health Document, "studies from Philadelphia, Chicago, and Newark discussed above provide persuasive evidence to strongly suggest that sources of lead other than paint, including that resulting from the presence of lead in gasoline, play an important role in childhood lead exposure. These other sources may be especially significant at levels of exposure below overt clinical poisoning." [57] Thus, the data allegedly supportive of the Administrator's dust and dirt hypothesis on the health hazard to children was not available until late 1973, as set forth in detail above.

These studies were absolutely crucial to the Third Health Document and to the Administrator's entire conclusions in regard to the lead danger to urban children. Each of these studies—Newark, Philadelphia, Chicago, and Rochester—came to EPA in October-November 1973 after the orders of this court and shortly before promulgation of the regulations on 28 November 1973.

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[52] 38 FED. REG. 33736 (subsection E of section II), App. at 4.

[53] Doc. 117, App. at 718. *See* App. at 139 (reference 38).

[54] Doc. 103, App. at 662. *See* App. at 135 (reference 14).

[55] Doc. 118, App. at 738.

[56] *Id.*, App. at 720.

[57] App. at 130.

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2. *The extent to which interested private parties, some of whom are petitioners here, were given or acquired actual notice of the existence of the scientific studies, were given notice as to which studies were to be relied upon by the Administrator in the Third Health Document, and commented thereon prior to the issuance of the Third Health Document itself.*

The Administrator argues, and our colleagues confidently assert, "There is nothing in Section 4 [5 U.S.C. § 553] that requires new notice whenever the agency responsibly *adopts* the suggestions of interested parties."[58] This is a salient point. The Administrator *did not adopt* the suggestions of the interested parties. *His prior conclusions* expressed in the First and Second Health Documents and in the regulations *were diametrically opposed* by all of the independent scientific minds in other government agencies, and by most of the affected industry, as represented by petitioners herein. Rather than adopting the suggestions of interested parties, the Administrator persisted in his conclusions as expressed in the regulations, although he did repropose the regulations (with slight modifications) on 10 January 1973 along with the Second Health Document.

More importantly, by October-November 1973 he was largely shifting his ground from the discredited scientific data of the First and Second Health Documents to the *new* data embraced in the Third Health Document. This is the crucial time at which informed comment from the best scientific minds in other government agencies and elsewhere should have been sought—unless EPA was irrevocably resolved to promulgate the restrictive regulations on lead which it had originally proposed years before, in spite of the barrage of unanimous critical com-

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[58] Court's opinion at 99 (emphasis added).

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ment from other government scientific minds, as well as interested outsiders.

With relation to the precise dates on which the scientific information later incorporated in the Third Health Document could possibly have become available to anyone, we summarize what the record shows—or fails to show.

(a) *Pilot Lead Isotope Studies*
and

(b) *Unpublished Study in Japan*—Since the formal period for comment expired 11 March 1973, and since the final regulations accompanied by the Third Health Document were promulgated on 28 November 1973, the dates when the two pilot lead isotope studies and the unpublished study in Japan were first placed in EPA's "public file" and transmitted to Ethyl under a FOIA agreement —4 October 1973, 6 August 1973, and 22 July 1973, respectively—indicate the limited opportunity available for effective comment to be received by EPA. Moreover, even these late dates do not fully reveal the inadequacy of EPA's compliance with section 553 since (1) filing papers under obscure headings [59] in a so-called "public file." (2) transmitting information to *one* interested party under a FOIA agreement, and (3) accepting a transcript from a scientific conference can hardly be equated with the public notice and comment mandated by the APA.[60] It is not surprising that nowhere in our colleagues' minute discussion of comments on all topics which were received by the Administrator do they claim that anyone besides Nalco, private or government, directed any comments (other than the conference transcript) to EPA on these three *new* studies. Yet EPA relies heavily on these studies in the Third Health Document. In fact, these are the first studies mentioned by the Administrator himself in his Preamble to the Regulations.

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[59] *See* note 34 *supra.*

[60] *See infra* at 42-50.

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(c) *The Chamber Studies*—This study was available in preprint form at the time of the Second Health Document. However, since public access to preprints is generally quite limited, the study probably was not available to the public in a meaningful sense until it was published in May 1973.

(d) *The Seven Cities Study*—The critical feature here, of course, is the "Additional Analyses of the Seven City Lead Study" of 15 March 1973. Besides the one EPA committee meeting,[61] which representatives of Ethyl attended, we do not know what, if any, opportunity for comment on the reanalysis was given other petitioners or interested parties. Since it was the "additional analysis" *only* which gave any statistically significant support to the Administrator's conclusions, the pertinent, relevant, and material question here is whether administrative due process was followed regarding this additional analysis after the close of comments on the Second Health Document.[62]

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[61] *See supra* at 23.

[62] The fact that in its reanalysis EPA "relied primarily on a finding reported in the original study" (Court's opinion at 104), does not change the fact that *only* the reanalysis makes the original finding statistically significant. In a lengthy footnote explaining the intricacies of statistical analysis, the majority opinion attempts to play down the difference between the statistically insignificant results of the original Seven Cities study and the statistically significant results attributed to the same study by EPA's reanalysis. Court's opinion at 104-05 n.112. Regardless of the mathematical percentages involved, we submit that reasoned decision-making requires scientists and administrators to rely only on observed relationships which can be statistically confirmed, *i.e.*, results which "the data support as showing a real effect, as opposed to . . . result[s] that might readily arise from sampling variation." *Id., quoting from* F. MOSTELLER, *et al.*, PROBABILITY WITH STATISTICAL APPLICATIONS 307 (2d ed. 1970).

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We conclude that the reanalysis marked a dramatic shift in the EPA's appraisal of the Seven Cities study—not, as the majority suggests, a mere reconfirmation of the validity of earlier data or a determination "that comments received during a preceding comment period [did] not undermine the validity of a particular piece of evidence." [63] The Preamble accentuates the importance of this shift by its reference to the Seven Cities study itself (before EPA's reanalysis) as an example of data cited by other experts as contrary to EPA's conclusions.

(e) *The Daines Study*—Adequate opportunity for comment was afforded because this study was in the same form in both the Second and Third Health Documents.

(f) *The Newark Studies*—The first part gave no support to the Administrator's conclusions, but in the second paper new and additional data was brought in. The second part was *in press in November 1973* and had *not even been published when the regulations were issued.* It is indisputable that no opportunity for comment by anyone on this important second study was afforded.

(g) *The Chicago, Philadelphia, and Rochester Studies* —Three of these four studies were first presented as conference papers on 1-2 October 1973, and the second Rochester study was still in press at the time the final regulations and Third Health Document issued. If any meaningful opportunity for comment on these studies was afforded, it is not reflected in the record.

Our colleagues attempt to minimize the importance of the Newark, Chicago, Philadelphia, and Rochester studies as a basis for the Administrator's conclusions, through a reading of the Administrator's Preamble designed to escape the fact that the Administrator was relying materially on these new, uncommented upon studies. The

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[63] Court's opinion at 104-05.

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court's opinion suggests that "[t]he only clear references to these studies, which bear on the validity of the dustfall hypothesis, occur in a portion of the Administrator's decision that addresses the question, 'What new information has become available since reproposal of the regulation and as a result of the additional comment period?' " [64] Accordingly, our colleagues conclude that "[t]hese additional studies . . . play[ed] no role in the Administrator's decision to regulate." [65]

That may be the "only clear reference" to our colleagues, but open eyes can read more. These studies were not just listed in the "new information" sections; they were discussed in the reliance portion, too. A comparison of the two critical sections of the Preamble reveals that the Administrator's language describing the evidence he is relying upon (found in subsection E of section II—entitled *"Does dust lead contribute to lead poisoning in children?"*) is repeated virtually verbatim in section V's description of *"[w]hat new information has become available since reproposal of the regulation . . .?"* [66] Hence, we logically conclude that the Administrator is referring to the same evidence in both places.

We are as well aware as are our colleagues that practical administrative procedure requires that at some point the responsible agency emerge from the decisionmaking process, and act. By act we mean that the agency should take *such action as is supported by the evidence in hand,* whether that action is to change drastically the petroleum refining industry and ultimately the type automotive engine manufactured in this country, or simply to let

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[64] Court's opinion at 106 (footnote omitted).

[65] *Id.* at 107 (footnote omitted).

[66] *Compare* 38 FED. REG. 33736, App. at 4 *with* 38 FED. REG. 33737, App. at 5.

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this portion of the economy remain unchanged until and if further evidence calls for changes.

We do not contend, as our colleagues suggest, that new information brought to the agency's attention too late to be made available during the formal comment period must be ignored or that an additional formal comment period is required whenever a review of recently developed information identifies new studies the Administrator finds supportive of his conclusions.[67] *To the contrary, we only submit that a responsible Administrator would not materially rely on recently acquired, uncommented upon studies*—especially when the results of previous studies had been undermined severely by the unanimous criticism of other independent government agencies. While the Clean Air Act does direct the Administrator to consider "all relevant medical and scientific evidence available to him" [68] before he issues a regulation, this instruction must be read in the context with the procedural requirements of the APA.[69] When he "considers" all medical and scientific evidence under the Clean Air Act, he "considers" in accordance with the Administrative Procedure Act. The Clean Air Act contains no exemption from the APA.

Indeed, there appears to be little, if any, difference in our position on EPA's responsibilities under the APA and our colleagues' position on this subject. We are not attempting to develop a novel procedural theory or "to transmute the *three-step* process established by § 4 [APA § 553] into a potentially unending and fruitless series of notices, comments, and notices of intent to rely on

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[67] *See* Court's opinion at 107 & n.117.

[68] Section 211(c)(1)(A), 42 U.S.C. § 1857-6c(c)(2)(A) (1970).

[69] *See* note 135 *infra*.

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comments." [70] Our colleagues excuse EPA's procedural shortcomings because, in their view, all new studies were *made available* to the public for comment at least three months before the Administrator reached his decision.[71] This, and not the notice and comment requirements of the APA, is the fundamental point of disagreement between the majority and the dissent in this case. As we have made abundantly clear, there was *no* meaningful opportunity for *informed* public comment on the Third Health Document. Rather than contending that "the public [must] have yet *another* opportunity to comment on [the new studies]," [72] we submit only that the public is entitled to *one* such opportunity if the Administrator intends to rely *materially* on this new, uncommented upon evidence. In other words, we submit that EPA may not keep secret information important to its decision, *i.e.*, the evidence on which it intends to rely materially. As our colleagues concede,[73] the authorities cited at 33-35 nn. 77-79 *infra* support this proposition. *Final agency action must be explained in terms of a record to which all interested parties have had an opportunity to contribute informed comment.*

It is important to understand that we fault EPA not because *all evidence* "was not specifically delivered to or called to the attention of petitioners when it arrived at EPA," [74] but because *certain new studies*, on which the Administrator intended to rely materially in the Third Health Document, were never brought to the public's attention in a manner that made *informed* public comment possible. EPA gave no notice indicating which

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[70] Court's opinion at 108 n.117 (emphasis in original).

[71] *Id.* at 100 n.102, 107, & 109 n.119.

[72] *Id.* at 107 (emphasis added).

[73] *Id.* at 107 n.117.

[74] *Id.* at 100 n.102.

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studies it intended to embrace (1) by placing every shred of lead-related evidence which it received in a public file or (2) by sending all of this evidence to one interested party pursuant to a FOIA agreement. Absent some form of notice indicating on which studies EPA intended to rely (*e.g.*, the type of notice furnished by the First and Second Health Documents), we are at a loss to understand how interested parties could formulate effective comments. Apparently our colleagues require the interested public to comment on *all* the evidence received by EPA or to guess which evidence the Agency will embrace and which it will ignore. In our view, the procedure, approved by a majority of this court, affords no opportunity for *informed* public comment.[75]

Our position does not conflict with the following, previously stated position of this court:

> In order that rule-making proceedings . . . be conducted in orderly fashion, information should generally be disclosed as to the basis of a proposed rule at the time of issuance. If this is not feasible, as in the case of statutory [or judicial] time constraints, information that is material to the subject at hand should be disclosed as it becomes available, and comments received, even though subsequent to the issuance of the rule—with court authorization, where necessary.[76]

In fact, one page earlier in the opinion containing this quotation Judge Leventhal states, "It is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data, or on data

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[75] Thus, our chart at 49 *infra* is not, as our colleagues assert (Court's opinion at 100 n.102) "fundamentally misleading."

[76] *Portland Cement Ass'n v. Ruckelshaus*, 158 U.S. App. D.C. 308, 327, 486 F.2d 375, 394 (1973), *cert. denied*, 417 U.S. 921 (1974).

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that, critical degree [*sic*], is known only to the agency." [77] Our problem with the data described in the Preamble and the Third Health Document does not lie in the fact that this data was too recently acquired or too late, per se. Instead, we base our objections on the identical grounds articulated by Judge Leventhal in *Portland Cement*, *i.e.*, EPA's data was "inadequate" (partly because of its inconclusive nature and lack of scientific validity and partly because it had not withstood the test of public scrutiny) and to a "critical degree, [was] known only to the agency."

When this court issued its order on 29 October 1973 for EPA to act within thirty days on the question of regulating lead additives in gasoline, we did not hint in what manner the Administrator should act, but presumably we intended that the Administrator should act on tested data he had been accumulating for some three years. Bearing in mind the fate EPA's previous data had suffered at the hands of the knowledgeable scientific community, it was not a responsible choice for the Administrator to resort to the most recently acquired, mostly never previously revealed, and never commented on data as the principal basis for his action.[78] It is particularly difficult to square the majority's analysis of the procedural issues in this case with the following language from a 1974 law review article by Judge Wright:

> If a particular rule rests on an extensive analysis of data or on a complex prediction . . . courts should require the agency to operate the three-step procedure of § 553 in a manner sensitive to the empirical

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[77] *Id.* at 326, 486 F.2d at 393.

[78] *See id.* at 326 & n.67, 486 F.2d at 393 & n.67; *Mobil Oil Corp. v. FPC*, 157 U.S. App. D.C. 235, 248 n.39, 483 F.2d 1238, 1251 n.39 (1973). *See generally* K. Davis, ADMINISTRATIVE LAW TREATISE § 15.10 at 402 (1958).

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> complexities at stake . . . . *Most important, the agency should not rely on any research methods or data which were not presented to the interested parties for comment or criticism.*[79]

Similarly, in an adjudicatory proceeding the Supreme Court has commented,

> A party is entitled . . . to know the issues on which decision will turn and to be apprised of the factual material on which the agency relies for decision so that he may rebut it. Indeed, the Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation.[80]

Much of the *data described in the Preamble and the Third Health Documents is data which had been shielded from adverse comment by the factor of time of acquisition. The fate of previous submissions to public scrutiny is an indication of the type comment this new data might likely have received.* While agreeing that at some point the Administrator must cease deciding and act, no valid administrative procedure would countenance launching an enterprise drastically affecting a substantial portion of our economy on such a shaky foundation as that relied upon in this case.[81]

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[79] Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 CORNELL L. REV. 375, 383 n.34 (1974) (emphasis added).

[80] *Bowman Transp., Inc. v. Arkansas-Best Freight Sys.*, 419 U.S. 281, 288 n.4 (1974).

[81] Can anyone imagine a responsible corporate executive launching a new enterprise with important economic consequences on data as flimsy and counter-indicative as EPA had here? (And private enterprise is supposed to take risks.) Or, a responsible government administrator—in any other field except one such as the environment, where emotional devotion to a "cause" is high—issuing regulations with as portentous effect as here on the same factual certainties that

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The interested private parties had some fear that just this might occur. On 19 October 1973, following the conference in early October at which several of the studies later relied on by EPA first were revealed, EPA "circulated" a "draft Third Health Document." [82] Ex-

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EPA had? We find these considerations relevant to the "arbitrary and capricious" standard we think should be applied here.

[82] Doc. 141. The court's opinion describes the draft Third Health Document as "substantially identical to the final draft" and goes on to explain,

> Chapters, I, II, V, VII, and VIII [the "Summary and Conclusions"] of this draft . . . differ only in minor wording changes from the final Third Health Document. Chapters III, IV, and VI of the final version contain a few additional inconsequential paragraphs and references. . . .

Court's opinion at 109 & n.121. Rather than quibble over the degree of similarity or dissimilarity between the draft and final document, we will simply describe with more specificity what the court refers to as "a few additional inconsequential paragraphs and references." Significantly, the three sections with the more extensive revisions bear these far from inconsequential titles: III. "Health Aspects of Lead Exposure"; IV. "Can an Acceptable Lead Body Burden be Defined?"; and VI. "Lead Exposure from Dustfall." The following chart roughly indicates the amount of revision performed on each of these sections:

SECTION III. Paragraphs: 4 new or revised paragraphs compared to 24 original paragraphs.

References: 3 new references added to 31 original references (all three dated 1-2 Oct. 1973).

SECTION IV. Paragraphs: 4 new or revised paragraphs compared to 12 original paragraphs.

References: 5 new references added to 10 original references (four dated 1-2 Oct. 1973; one dated Mar. 1973).

SECTION VI. Paragraphs: 13 new or revised paragraphs compared to 26 original paragraphs.

[Continued]

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actly to whom this draft was circulated, the record does not reveal. Ten days later came this court's order, making certain that some action on some basis would be taken by EPA within thirty days. On 19 November 1973 counsel for petitioner E. I. Du Pont requested that "in the event that these regulations . . . are based upon different scientific and technical arguments and data than those enunciated in the January 10, 1973, statement . . . [they] be given *an opportunity to comment* on the *new basis* for the regulations *in writing and at a public hearing* prior to their final promulgation." [83]

Our colleagues assert that such a request was an effort to evade the mandate of this court that regulations issue within thirty days. We think that petitioner Du Pont recognized the same point that we make here, that if indeed the Administrator had discovered a *new*

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[82] [Continued]

References: 6 new references added to 41 original references (one in print; one in prepublication draft; others dated 28 Aug. 1973, Dec. 1972, 1972, and May 1971).

There is nothing in the Administrator's decision (*i.e.*, the Preamble) or the Third Health Document that indicates that EPA would have made the same decision without the new supportive evidence indicated in the chart above. Unless the Administrator makes it clear that *he* considered this additional evidence "inconsequential," we cannot excuse his failure to make it available for public comment. An agency may not keep secret evidence on which it intends to rely to support its decision.

[83] EPA denied this request by a letter dated 4 December 1973, after the regulations were promulgated. On 21 November the Lead Industries Association teletyped the Administrator "Final lead in gasoline regulations now being circulated represent *substantial changes* in both the lead phase down schedule and supporting documentation. The major changes *deserve public comment* regarding their validity." (emphasis in original.)

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basis for the regulations, then responsible, practical administrative procedure demanded that the interested parties be given the same opportunity to comment on the new basis as they had on the old. It certainly, as a practical matter, does no good for an agency to propose an action, support it with data which is severely criticized, abandon that supporting data for new, fail to subject the new data to informed comment, and then promulgate the same proposed regulations on the basis of new data.[84] Nor is it valid thereafter to claim that full opportunity for comment has been afforded.

The court's opinion also asserts that "[t]he early October preparation of a draft decision and a draft Third Health Document, both in obviously near final form, belies any contention that this court's 30-day order . . . forced EPA to rush into a decision it was not yet ready to make."[85] Aside from the fact that the record fails to reveal who received copies of these eleventh-hour docu-

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[84] The medical director of Nalco, the only one to comment on the new EPA health data circulated 19 October 1973, knew exactly what the agency was up to: "The present EPA health document is one of many final or draft documents which we have had the opportunity to review. In each instance the document has presented a different basis for the same summary and conclusions." Doc. 821 at 44.

Compare the action of the EPA here with its action in *Environmental Defense Fund, Inc. v. EPA (Coahoma)*, 160 U.S. App. D.C. at 128, 489 F.2d at 1252. See note 28, *supra*. There the Administrator accumulated a mass of data, much of it conflicting, pondered it, and drew his conclusion. Here the Administrator advanced proposed regulations, saw his supporting data riddled by other scientific minds, shifted twice the supporting rationale, and three years later came out with virtually the identical regulations he had advanced three years earlier. This court respected the Administrator's decision in *Coahoma*, but here the Administrator's action calls logically for a different result.

[85] Court's opinion at 109 n.121.

ments, we submit that it was not at all obvious that they were in "near final form." The cover page of the draft Third Health Document carried the following inscription bearing on its finality: "*DISCLAIMER*: THIS DOCUMENT IS A PRELIMINARY DRAFT. IT HAS NOT BEEN FORMALLY RELEASED BY THE AGENCY AND SHOULD NOT BE CONSTRUED TO REPRESENT AGENCY POLICY . . . ."[86] Moreover, as to the draft decisions referred to in the court's opinion, both were internal EPA briefing memoranda, one dated November 1973 and the other dated October 1973.[87] Finally, we reject the majority's assertion that this court's thirty-day order did not force EPA to rush into a precipitate decision. On this point the shaky evidentiary foundation of the Third Health Document speaks for itself.[88]

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[86] Doc. 141 (emphasis in original).

[87] Docs. 485 & 486, App. 1474-1502, 1502-16.

[88] See our discussion of the evidence relied upon by EPA *infra* at 61-82. Recent history would indicate that the prime mover behind implementation of the Clean Air Act has not been Congress or EPA, but the courts—specifically this court:

> The agency wrote the controversial clean-air regulations in 1973 only after U.S. Court of Appeals here [Washington, D.C.] ordered it to do so. Subsequently, too, the EPA readily granted cities such as Los Angeles more time to meet the standards. Environmentalists went to court to force the EPA to enforce the deadline.
>
> The agency even seems to have felt compelled to apologize for its displays of vigor. In announcing the auto-pollution rules, including the requirement for drastic gas rationing in Los Angeles, William Ruckelshaus, who was the EPA administrator, blamed the courts: "I know this is controversial, but I am under a court order and this is the only demonstrable way to meet the national clean-air standards."

House, *Lost in a Smog Bank*, Wall Street Journal, 16 Jan. 1976, at 4, col. 3.

It is instructive to see the result of EPA's action in circulating in some quarters a draft Health Document containing new data in late October, but affording no formal comment period. According to the certified index to the record, precisely twenty persons, corporations, or entities made twenty-four written submissions to EPA during the sixty-day period up to and including 28 November 1973, the date upon which the regulations were promulgated.[89] This compares to at least 218 persons, corporations, agencies, or other entities that commented on the regulations on a prior occasion. Of the twenty-four submissions, fully nine were *dated* 26 November 1973 or 28 November 1973; it is thus virtually impossible for any of them to have been considered by the Administrator. Only seven submissions were dated 18 November or earlier. Only two submissions were from agencies of the federal government, a letter from the Secretary of Transportation dated 26 November 1973[90] and two pages of comments from the Treasury

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[89] Interestingly, the majority opinion cites one other submission—a one page letter from the Acting Deputy Assistant to the Secretary of Interior—to support its position that "comments [on the draft of the Administrator's decision and the draft Third Health Document] *were received and acted upon.*" Court's opinion at 109 & n.122 (footnotes omitted and emphasis added). We are curious how EPA "acted upon" or considered this letter, which severely criticized EPA's current draft of the regulations, when the letter bears a *7 December 1973 date.* We can only surmise that this comment had no profound effect on the *28 November 1973* regulations.

[90] Secretary Brinegar raised serious questions as to the economic impact of the contemplated regulations: ". . . in view of the emergency that we now face it would be unwise to undertake actions that could work in the opposite direction [to increasing supplies], as does the lead reduction schedule. . . . Do not the extraordinary recent changes in energy supply, demand, and price relationships force us to reappraise and re-analyze such a far reaching decision?"

[Continued]

Department dated 19 November 1973.[91]

The content of these twenty-four submissions is equally illuminating. After carefully examining each of these submissions, we found only one, Nalco's review of EPA's health position dated 19 November 1973,[92] to be a substantive critique of EPA's draft Third Health Document. In fact, it was the *only* submission which made any significant comment on EPA's *health position* at all. All but four of the other submissions focused upon the energy or economic costs of the proposed regulations. Even these comments were quite short, ranging from one page (seven of the letters or telexes) to four pages (one of the letters) in length. To the extent any of these nineteen submissions mention the health issue (most do not and the few that do merely state their disagreement), *none mention or refer to the draft Third Health Document.* Three of the four remaining submissions were from Ethyl's counsel. One was a letter dated 29 October 1973 calling EPA's attention to two articles which EPA had so far overlooked;[93] one was an unedited transcript of the October conference on low-level lead effects mailed to EPA on 24 October 1973;[94] and the third was a

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[90] [Continued]

He mentioned the health problem only to query: "With future gasoline usage now likely to fall significantly, . . . is it not necessary to re-calculate future total lead emissions and their possible health hazards?" Doc. 1269, App. at 2651.

[91] Doc. 1084, App. at 2577. Like the Secretary of Transportation's letter, the Treasury Department's comments were addressed to the economic impact of the regulations, and not to EPA's health position. EPA's draft Third Health Document is not referred to in either agency's communications.

[92] Doc. 821.

[93] Doc. 1090.

[94] Doc. 433.

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letter dated 12 October 1973 requesting EPA to place in its files the individual presentations made at the October conference, rather than just the abstracts.[95] The only other health-related submission during this period was the collection of abstracts referred to in Ethyl's 12 October letter.[96] None of these submissions mentions or comments on the draft Third Health Document.[97]

Despite this paucity of comment, our colleagues assert that "[a]ll significant new information developed during the rulemaking in this area on the frontiers of scientific knowledge was *made available* to petitioners and the public for comment *well in advance* of issuance of the final regulations on November 28, 1973. Thus both the requirements and the spirit of Section 4 [APA § 553] were complied with." [98] With this conclusion behind them,

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[95] Doc. 1089.

[96] Doc. 1092.

[97] Our colleauges infer from the date of Ethyl's second letter to EPA, 29 October 1973, that before this letter was written Ethyl must have received a copy of the 19 October draft Third Health Document (through the FOIA agreement or otherwise). Court's opinion at 109-110 n.123. The record is silent on this point, and the letter from Ethyl's counsel (Doc. 1090) does not even imply, much less state, that Ethyl had any knowledge of the 19 October draft.

[98] Court's opinion at 100 (emphasis added and footnote omitted). In a similar vein, the court's opinion concludes,

> The record in this case clearly demonstrates EPA fully satisfied the requirements of administrative due process. In fact, EPA's efforts to elicit informed comment on its proposed action went far beyond the measures it was required to take. All health-related documents, including internal EPA policy memoranda, were made public upon receipt, and comments on the documents were accepted until the date of final promulgation . . . .

Id. at 108-109 (footnotes omitted).

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our colleagues are able to avoid the key procedural issue raised by this record, *i.e.*, whether the Administrator may rely on information not previously made available in any meaningful sense to the petitioners or the public without violating both the letter and the spirit of the APA.[99] Apparently, our concept of *making information available* to the public *well in advance* of promulgation and our understanding of the compliance requirements of section 553 differ considerably from those of our colleagues.

The court's opinion strives strenuously to prove that three of the five petitioners received notice in fact of the Third Health Document, or at least portions thereof. They assert that "petitioner Ethyl was directly furnished with all such documents as a result of a Freedom of Information Act . . . suit." [100] We do not believe that agency compliance with the APA can rest on individual interested parties filing FOIA suits. If the APA is to avoid becoming a docile paper tiger, it can not rely on the enforcement teeth of other federal statutes.[101]

Furthermore, of course, as shown by the dates of many critical documents relied upon by the Administrator (including, *inter alia*, one which was not even included

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[99] The court devotes merely the following one-sentence footnote to the most significant procedural issue in this case:

> Since all material information was made available for comment by petitioners and the public, it is not necessary for us to determine whether the Administrator may rely on information not previously made available.

Court's opinion at 100 n.101.

[100] *Id.* at 108-09 n.118.

[101] See a discussion on the limitations of the FOIA as a discovery tool in informal rulemaking in 85 YALE L. J. 38, 69-70, 84-86 (1975).

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in the Third Health Document;[102] two which were mentioned in the Third Health Document, but had not even been published when the regulations were issued;[103] and four which came to light only after the October 1973 conference[104]) it is clear that Ethyl *did not have adequate time to prepare effective comments, even if one assumes that Ethyl knew that EPA intended to rely on these documents* when it promulgated the final regulations. In addition to Ethyl, our colleagues point to "comments" from petitioners NPRA and Nalco.[105] Regarding NPRA's submissions, our colleagues are not consistent in their assertions, since they seem to agree that these comments related only to the shift from leaded pool averaging to total pool averaging, and *not* to *EPA's health position.*[106] Unlike other aspects of the regulations, the shift from leaded pool averaging to total pool averaging did not incorporate and rely on new information. Therefore, this particular change in the regulations managed to avoid the procedural infirmities that plague all other aspects of the regulations, and NPRA's comments on this change became irrelevant to the procedural issue involved in this case. On the other hand, as we indicated above, *Nalco's comments represent the one and only sub-*

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[102] The unpublished study in Japan, Doc. 468, App. at 1092.

[103] The second paper of the Newark studies, Doc. 95, App. at 626; one of the Rochester studies, Doc. 118, App. at 720.

[104] The first pilot lead isotope study, Doc. 113, App. at 678; the Chicago screening, Doc. 117, App. at 718; the Philadelphia study, Doc. 103, App. at 662; one of the Rochester studies, Doc. 118, App. at 738.

[105] *See* Court's opinion 97-99 nn.99 & 100, *citing* Doc. 556, App. at 1962 & Doc. 1259 (NPRA); court's opinion at 102 n.106 & 103 n.108, *citing* Doc. 821 (Nalco).

[106] *Compare id.* at 99 n.100 *with id.* at 97-98 n.99. The only other NPRA submission cited in the court's opinion, Doc. 1259, deals only with the economic analysis prepared for EPA by Bonner and Moore Associates, Inc.

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stantive critique of the draft Third Health Document received by EPA before promulgation of the regulations.

In their attempts to demonstrate that "comments [on the Third Health Document] were received",[107] our colleagues equate the unedited transcript of the October conference, which was submitted by Ethyl to EPA, with comment on the new studies presented at that conference.[108] Similarly, they imply that Ethyl's submission of a transcript from the EPA committee meeting where the Seven Cities reanalysis was first discussed amounted to comment by Ethyl on the reanalysis.[109] We simply cannot accept the court's conclusion that the submission of these unedited transcripts amounts to even a form of comment. Moreover, if these unedited transcripts can be characterized as some form of comment, surely they are not such an effective form that they prove beyond peradventure that EPA afforded the petitioners (not just Ethyl) and *all other interested parties* a meaningful opportunity for effective comment.

Strangely, our colleagues seem to feel that EPA "went far beyond the measures it was required to take" by placing new information in the so-called "public file" and thereby making it "available for comment and criticism." [110] To the contrary, we submit that (1) placing information in a public file (not to mention indexing that information under obscure headings) and (2) making information "available for comment and criticism"

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[107] *Id.* at 109.

[108] *Id.* at 102 n.106 ("Ethyl . . . submitted comments on [the first pilot lead isotope] study in the form of a transcript of the October conference. Doc. 433.")

[109] *Id.* at 105 & n.114. See our previous brief remarks on this transcript *supra* at 23.

[110] *See, e.g.*, Court's opinion at 100 & 108-09.

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affords interested parties *no notice* whatsoever that EPA *will rely* on this information. *This intent to rely was only noticed in the Health Documents, on the last of which no effective comment was possible.* We can only wonder how many thousands of pieces of paper were "placed in the public file" that EPA never mentioned in any Health Document. Conceivably, under the court's view of administrative procedure the burden of sifting through hundreds of pounds of poorly indexed paper and guessing which studies will be relied upon can be shifted from an agency to the interested parties through the simple device of a "public file."

In summary, we find the conclusion undeniable that no effective comment on EPA's revised health position took place—nor could it have taken place—in the brief period just prior to promulgation, as the court's opinion would have us believe. The absence of any comment on EPA's new health data (with the sole exception of Nalco) gives rise to the inference that either circulation of the draft Third Health Document was limited to a more receptive audience than previous circulations had addressed or that the time between receipt of the draft and promulgation of the regulations was not sufficient to permit effective comment. The total absence of any comment on EPA's new health position by any government agency, the source of previous unanimous caustic criticism, is most significant.

As indicated by the heading of this opinion subsection, it is not enough under the Administrative Procedure Act merely to make the scientific data "available" to the public and all interested parties. *First,* the claimed "availability" here boils down to a compelled furnishing of data to *one* interested party under the Freedom of Information Act and the placing of hundreds of miscellaneous documents—scientific studies, papers, published

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articles, etc.—in a poorly indexed [111] dust bin of a file in the public rooms of the Environmental Protection Agency. *Second*, there was *never any notice*—and our colleagues do not and can not contend that there was—*on which data* out of the great miscellany EPA *would rely* until the Third Health Document was published simultaneously with the regulations. *Third*, the opportunity to comment effectively on the new data on which EPA ultimately relied was farcicial, as our detailed discussion above nails down.

Since Nalco was able to prepare and submit a substantive critique of the draft Third Health Document on 19 November 1973, obviously Nalco somehow received actual notice of the existence of the draft Third Health Document and the new evidence therein. (Perhaps Nalco's representatives were luckier or more adept than the representatives of other interested parties when it came to sifting through poorly indexed documents.) The record, however, does not indicate that any other interested party received notice of the existence of this new evidence, and clearly, no interested party, including Nalco, received any notice that EPA intended to rely on these new studies. As we mentioned earlier, on its cover page, the 19 October draft bore the following notation:

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[111] *See* note 34 *supra*. Describing how EPA typically assembles a record, William F. Pederson, Jr., an attorney with EPA's Office of General Counsel, has stated,

> At every stage . . . the tendency of the record is to increase in length and become less organized. Factual materials, documents describing the development of policy, and documents included simply to quiet suspicions of bad faith will all be jumbled in together.

85 YALE L. J. 38, 70 (1975). These unwieldy and disorganized records plague not only the interested parties, but also the courts.

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DISCLAIMER:

> THIS DOCUMENT IS A PRELIMINARY DRAFT. IT HAS NOT BEEN FORMALLY RELEASED BY THE AGENCY AND SHOULD NOT BE CONSTRUED TO REPRESENT AGENCY POLICY. IT IS BEING CIRCULATED FOR COMMENT ON ITS TECHNICAL ACCURACY AND POLICY IMPLICATIONS.[112]

Accordingly, Nalco wrote in the introduction to its substantive comments, "It is understood that these documents [the draft Health Document and the draft regulations] are preliminary drafts and have not been formally released by the agency and should not be construed to represent Agency policy." [113] On the basis of previous EPA practice in regard to the First and Second Health Documents, until EPA formally released the Third Health Document as representing the Agency's position, no one had any notice of EPA's intent to rely on new evidence.

To emphasize the gross procedural irregularities approved by the majority of this court, in the following chart we capsulize what the record reveals—or fails to reveal:

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[112] Doc. 141 (emphasis in original).

[113] Doc. 821 at 90.

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PAGES FOUND VERTICALLY

	Pilot Lead Isotope Study #1	Pilot Lead Isotope Study #2	Unpublished Study in Japan	Seven Cities Reanalysis	Newark, Chicago Philadelphia and Rochester Studies
Notice of					
(a) the evidence's existence	Ethyl (4 Oct. 1973) Nalco (19 Oct. 1973) Other interested parties (none)	Ethyl (6 Aug. 1973) Nalco (19 Oct. 1973) Other interested parties (none)	Ethyl (22 July 1973) Other interested parties (none)	Ethyl (25 Feb. 1973) Nalco (19 Oct. 1973) Other interested parties (none)	Nalco (19 Oct. 1973) Other interested parties (none)
(b) EPA's intent to rely on this evidence	none	none	none	none	none
Time Available for Comment After Notice of					
(c) the evidence's existence	Ethyl (55 days) Nalco (39 days) Other interested parties (none)	Ethyl (114 days) Nalco (39 days) Other interested parties (none)	Ethyl (129 days) Other interested parties (none)	Ethyl (9 mos.) Nalco (39 days) Other interested parties (none)	Nalco (39 days) Other interested parties (none)
(d) EPA's intent to rely on this evidence	none	none	none	none	none

In no previous case, environmental or otherwise, has this court tolerated such "public notice" and "opportunity to comment" as it sanctions here. From the pages of the court's opinion there seeps the theme that this is an environmental case; hence, the court like the agency need not labor by the usual rules. We recognize no such exemption for this or any other type case; certainly Congress did not give it to us; we know that adherence to proper prescribed procedure is the soundest route to a correct substantive result.

II. The Legal Standard

A. *The Statute—Its Interpretation*

Section 211(c)(1) of the Clean Air Act authorizes the EPA Administrator to

> control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive for use in a motor vehicle or motor vehicle engine (A) if any emission products of such fuel or fuel additive will endanger the public health or welfare. . . .[114]

The initial question presented is whether the Administrator properly interpreted this legal standard when he made the factual determinations upon which these regulations must be predicated.

The petitioners contend that the "will endanger" standard requires a determination that lead motor vehicle emissions, in and of themselves, pose a direct and provable health hazard to significant portions of the general public. By contrast, if it can only be demonstrated that lead emissions contribute to a health hazard, the Administrator is limited to acting under section 202,[115] which deals

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[114] 42 U.S.C. § 1857f-6(c)(1) (1970).

[115] 42 U.S.C. § 1857f-1 (1970).

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with emission standards imposed on new car manufacturers, and sections 107 through 110 of the Clean Air Act,[116] which deal with ambient air quality standards.

The Administrator stated his interpretation of the statutory language when he issued the regulations:

> It is the Administrator's view that the statutory language quoted above does not require a determination that automobile emissions alone create the endangerment on which controls may be based. Rather, the Administrator believes that in providing this authority the Congress was aware that the public's exposure to harmful substances results from a number of sources which may have varying degrees of susceptibility to control.[117]

As far as this statement goes, we deem it correct. To recognize lead in the ambient air as but one possible source of lead in the human body is merely to recognize undisputed fact. But to argue that, because there are multiple sources of lead, a chain of causation from lead in the air produced by auto emissions to a level of lead in the blood high enough to be dangerous to health need not be established is totally fallacious. We are not clear that the Administrator really argues this, but it is certain that our colleagues, in order to bolster the agency's position, have throughout their opinion embraced this fallacy.

Our reading of the language of the Act, its legislative history, and the administrative record lead us to the view that section 211(c)(1)(A) requires the Administrator to conclude "after consideration of all relevant medical and scientific evidence available to him" that a fuel or fuel additive causes an emission which *causes* a significant health hazard to a substantial portion of the gen-

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[116] 42 U.S.C. § 1857c-2 through 42 U.S.C. § 1857c-5 (1970).

[117] 38 FED. REG. 33734, App. at 2.

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eral population before he can control or prohibit the use of particular fuels or fuel additives.

Logically, only if the Administrator can say that a fuel additive causes a significant health hazard can he say that controlling or prohibiting such fuel additive would reduce significantly such health hazard. Whether we term the Administrator's decision one of "assessment of risks," as our colleagues urge, or whether we emphasize that such decision must be based on "facts," the *causal connection between lead emissions and the harm* must be established by relevant scientific and medical evidence.

When we refer to the necessity under the statute of showing that a fuel additive *causes* a health hazard, we do *not* mean that the statute requires a showing that the fuel additive (lead) causes a health hazard *without consideration of other sources of lead in the human body having their determined effect also.* To interpret the statute in this manner would be preposterous on its face, for as we shall discuss later in Part IV, on EPA's data most of the lead in the human body comes from dietary sources, food and drink. We think that the statute does require that, before the Administrator can prescribe the regulations involved here, he must find that the lead from auto emissions by itself or alone contributes a *measurable increment of lead* to the human body, and that *this measurable increment causes a significant health hazard.*

To repeat, only if the Administrator can say that an identifiable measurable increment of lead in the human body is derived from auto fuel additives and that *this measurable increment of lead itself* (taking into consideration all other sources of lead) *causes* a significant health hazard, can the Administrator claim that controlling or prohibiting lead would *reduce* significantly such health hazard.

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To us all analysis leads inescapably to this conclusion, yet the court's opinion endeavors to avoid this by resorting to two obfuscating dichotomies (perhaps the same distinction expressed in two ways). First, the opinion attempts to separate *actual* from *potential* harm, and, second, to separate *risk* from *fact*. "[T]he 'will endanger' standard is precautionary in nature and does not require proof of actual harm before regulation is appropriate." [118] "[T]he power to assess risks, without relying solely on facts, flows inexorably from the nature of the 'will endanger' standard." [119] We submit no such separation occurs in the real world, and if the Administrator proceeded on any such fanciful theory, it is an instance of his failure to discern the intent of Congress manifested by the words "will endanger."

As to the first distinction, there is no distinction possible here between actual and potential, between past and future harm. The Administrator is dealing with a *continuing situation*. If there can be found potential harm from lead in exhaust emissions, the best (and only convincing) proof of such potential harm is what has occurred in the past (either in 50 years of practical usage or in laboratory experimentation), from which the Administrator can logically deduce that the same factors will produce the same harm in the future. For the court's opinion to hold that the Administrator can dispense with proof of actual harm, *i.e.*, what has occurred in the past, and can nevertheless somehow determine *potential* harm, is to grant the plainest license for the wildest speculation. We have always thought scientific conclusions, above all, demanded proof by events recorded and observed.[120]

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[118] Court's opinion at 30-31 (footnote omitted).

[119] *Id.* at 37.

[120] Poets and politicians concur: "All our past acclaims our future" (Swinburne); "I know no way of judging of the future but by the past" (Patrick Henry).

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The court's second asserted dichotomy, risks versus facts, is equally indefensible in logic. All true risk assessment is based on facts and nothing else.[121] Those professional risk-assessors, the professional sports gambling fraternity, would smile at any other theory. To the extent that hunch and intuition enter into any final decision, these are separate factors outside of any scientific risk calculation.

Our colleagues apparently find it necessary to legitimatize the Administrator playing hunches. They assert, "Danger is a risk, and so must be decided by assessment of risk *as well as* by proof of facts."[122] Of course the Administrator assesses risk—from the facts as he knows them. The question here is how much he knows. To the extent the agency found it necessary to make an "assessment of risk as well as [rely on] proof of facts," the agency was frankly just speculating. No reviewing court can countenance this. If such agency decision is not "arbitrary and capricious," what decision could be? It is precisely a devotion to *facts*, not hunches, that distinguishes the professionals from the amateurs in assessing risks; we deem the Administrator to have been intended by Congress to be a "professional."

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[121] In all games of chance in which theoretically the factor of human control is not present, *e.g.*, roulette, dice, the fall of cards, the risk of a given event occurring or not occurring can be calculated with mathematical certainty. In those games in which human or animal skill is presumed to predominate, *e.g.*, football, basketball, horse racing, the *facts* as to the physical conditions and mental attitude of the contestants are avidly sought by the professional risk-assessors; it is on the basis of known *facts* that the initial odds are fixed.

[122] Court's opinion at 45 (emphasis added).

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B. *Threshold Factual Determination Required*

EPA, relying upon our recent opinions in *Amoco, supra,* and *Industrial Union Department, AFL-CIO v. Hodgson,*[122] argues:

> In the present case, as in *Hodgson*, the EPA must determine what amount of lead it should permit to be used as additives to gasoline. Here, too, "reliable data is not currently available with respect to the precisely predictable health effects of various levels" of lead which the EPA could permit to be used. The Agency's decision to require a gradual diminution in the permissible amount of lead is, in the last analysis, a policy judgment "concerning the relative risks of underprotection as compared to overprotection."
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> . . .
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> The regulations here reflect reasoned judgment on a border area of scientific knowledge and a policy choice in favor of protecting people exposed to automobile exhausts and particularly urban children. This judgment should be upheld.[124]

In essence, it is argued that the "will endanger the public health . . ." standard is a delegation of quasi-legislative power to the Administrator and not a requirement that he reach a reasoned determination purely on the scientific and medical data.

It is manifest that Congress wished the Administrator's threshold determination under section 211(c)(1)(A) to be a reasoned factual determination based solely on the medical and scientific evidence. This is made quite clear by subsection 211(c)(2)(A) which emphasizes that "[n]o fuel, class of fuels, or fuel additive may be controlled or prohibited by the Administrator pursuant to clause (A) of paragraph (1) except after consideration of all relevant medical and scientific evidence available

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[122] 162 U.S. App. D.C. 331, 499 F.2d 467 (1974).

[124] Reply Brief at 44-45.

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to him. . . ." By directing the Administrator to consider "all relevant medical and scientific evidence" before deciding to institute controls, the Congress must have intended that such evidence act as the basis for his determination.

If the intention had been to permit him to make "an essentially legislative policy judgment, rather than a factual determination . . . ," [125] some indication of this should have appeared in the statute. Other sections of the Clean Air Act closely related to section 211 do contain some indication that a broad discretionary power is being vested in the Administrator. Section 108 authorizes the Administrator to set air quality criteria for each air pollutant "which *in his judgment* has an adverse effect on public health or welfare . . . ." [126] Section 202 authorizes the Administrator to set standards for each automobile emission "which *in his judgment* causes or contributes to, or is likely to cause or to contribute to, air pollution which endangers the public health or welfare." [127]

By the same token, neither section 108 nor section 202 requires the Administrator in his *threshold determination* to consider either scientific or medical evidence. Section 108 air quality *criteria* which EPA ultimately promulgated are required, however, to "*reflect* the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, *in varying quanti-*

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[125] *Industrial Union Dep't, AFL-CIO v. Hodgson*, 162 U.S. App. D.C. 331, 339, 499 F.2d 467, 475 (1974).

[126] 42 U.S.C. § 1857c—3(a)(1)(A) (1970) (emphasis added).

[127] 42 U.S.C. § 1857f—1(a)(1) (1970) (emphasis added).

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ties." [128] Section 108 therefore requires a factual determination based on "the latest scientific knowledge" in establishing criteria, while permitting wider discretion in making the original threshold determination as to which pollutants to list.

In conclusion, we believe that the threshold determination whether an emission "will endanger the public health . . ." does turn and was intended by Congress to "turn crucially on factual issues" and not upon "choices of policy."

III. Scope of Review

EPA in promulgating these regulations followed the informal rulemaking procedure outlined in the Administrative Procedure Act, 5 U.S.C. § 553.[129] Since the Clean Air Act neither provides for review "on the record of an agency hearing" nor provides specifically the standard of judicial review, our scope of review of these regulations is limited to a determination of whether "agency action, findings . . . [or] conclusions . . . [are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." or "in excess of statutory jurisdiction, authority, or limitations, or

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[128] 42 U.S.C. § 1857c—3(a)(2) (1970) (emphasis added).

[129] Section 553(c) provides:

> After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

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short of statutory right," or "without observance of procedure required by law." [130]

It is well recognized that in reviewing the record we are not to substitute our judgment for that of the Administrator.[131] Thus, we are required to affirm agency determinations with which we disagree. However, we are also under an obligation not to act as a rubber stamp of agency rulemaking action. As a result, in reviewing agency rulemaking under section 553, we are obligated to engage in a "substantial inquiry," and "inquiry into the facts is to be searching and careful. . . ." [132] As the Supreme Court has indicated, we "must consider whether the decision [of the administrative agency] was based on a consideration of the relevant factors and whether there has been *a clear error of judgment.*" [133]

Certainly a determination made in the absence of any evidence in the record to support it would lead a reviewing court to conclude that a "clear error of judgment"

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[130] 5 U.S.C. §§ 706(2) (A), (C), & (D) (1970).

[131] *Calcutta E. Coast of India and E. Pakistan/U.S.A. Conference v. FMC*, 130 U.S. App. D.C. 261, 264, 399 F.2d 994, 997 (1968).

[132] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415, 416 (1971).

[133] *Id.* (emphasis added). This statement of the scope of review was reaffirmed very recently by a unanimous Supreme Court in *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 284-86 (1974). *See also Portland Cement Ass'n v. Ruckelshaus*, 158 U.S. App. D.C. 308, 335, 486 F.2d 375, 402 (1973): "We cannot substitute our judgment for that of the agency, but it is our duty to consider whether 'the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.' Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416, 91 S.Ct. 814, 824, 28 L.Ed. 2d 136 (1971). Ultimately, we believe, [*sic*] that the cause of a clean environment is best served by reasoned decision-making."

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had occurred. However, a reviewing court could reach a similar conclusion in the presence of some evidence supporting the agency determination.[134] Since a court must review "the entire record," it may well be that the evidence detracting from the agency's conclusion is so overwhelming or so persuasive, or the agency's approach so one-sided, or the decision-making process so flawed, that a reviewing court must conclude that the agency erred in the exercise of its rulemaking power.[135] Or, if there is

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[134] The Supreme Court made this quite clear in *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 284 & 285 (1974) (footnote omitted):

> The District Court properly concluded that, though an agency's finding may be supported by substantial evidence, based on the definition in *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, it may nonetheless reflect arbitrary and capricious action. There seems, however, to be agreement that the findings and conclusions of the Commission are supported by substantial evidence. The question remains whether, as the District Court held, the Commission's action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" as provided in 5 U.S.C. § 706(2)(A).
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> . . .
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> Under the "arbitrary and capricious" standard the scope of review is a narrow one. A reviewing court must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. . . . Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park* v. *Volpe*, *supra*, at 416. The agency must articulate a "rational connection between the facts found and the choice made."

The lack of a connection between facts found and choices made is the Agency failure we find here.

[135] The following exchange during the debate on the Clean Air Act typifies the Congressional understanding that this court should review for clear errors of judgment:

[Continued]

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an essential point or element missing in the logical progression toward the conclusion that the agency reaches,

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[135] [Continued]

Mr. ROGERS of Florida. . . . We have said that if there is a component part of the gasoline or if there is an additive which the facts show will affect the public health, and medical and scientific facts show this, or will prevent the emission standards from being met, the Secretary may act as to the component part or that additive.

Mr. WAGGONNER. What appeals are made available to the manufacturer of an engine or the producer of a fuel, if they take issue with the findings of the Secretary of Health, Education, and Welfare?

Mr. ROGERS of Florida. They have the Administrative Procedure Act.

Mr. WAGGONNER. And only the Administrative Procedure Act?

Mr. ROGERS of Florida. And an appeal to the court, from the Administrative Procedure Act.

. . .

Mr. WAGGONNER. Not in all cases do people have the right of appeal to the court under the Administrative Procedure Act. In some instances under the Administrative Procedure Act the decisions are final, when they render a decision.

Mr. ROGERS of Florida. I believe they would in this instance.

. . .

Mr. STAGGERS. I think the gentleman from Louisiana was worried about the fact that this would be a hard ruling made in the courts. Of course, *these matters come up under the Administrative Procedure Act, and then they have recourse to the courts.* If they feel, after all of the hearings have been laid before them, that these were not the facts and *that the ruling was wrong, the court will have the final decision.*

116 CONG REC. (Part 14) at 19230-31 (House) (10 June 1970) (emphasis added).

then the agency's action likewise may be arbitrary or capricious, because it is not supported by a logical thought process.

In these consolidated environmental protection cases the thought process by which an agency reaches its conclusion on informal rulemaking resembles a chain. If there is a link missing, then the agency, to reach the conclusion that it did, was required to take an arbitrary jump in its logic to reach that conclusion. To illustrate, we have the admitted fact that there is lead in gasoline which goes into the automobile tank. At the other end of the thought progression there is the scientific conclusion that too much lead in the human blood level is harmful—although there seems to be no agreed conclusion as to exactly what that blood level is (for this case, we assume the EPA level correct). Logically, as we view the scientific evidence, the chain of transmittal of the lead in the auto tank to the lead in the bloodstream is vital on the issue before us—whether there is valid reasoning based on evidence to sustain a finding that lead additives will endanger public health. The standard of "will endanger" makes the existence or nonexistence of a scientifically demonstrated chain of transmittal (and not a mere pattern of guesswork) decisive. For if no such scientifically proved chain exists, the Administrator's decision can only be arbitrary and capricious.

The recent First Circuit case, *South Terminal Corporation v. EPA*,[136] supports our application of the "clear error of judgment" standard of review to the Administrator's determination here. In *South Terminal* the court was called upon to review the Metropolitan Boston Air Quality Transportation Control Plan promulgated by the Administrator under section 110 [137] after the Common-

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[136] 504 F.2d 646 (1st Cir. 1974).

[137] 42 U.S.C. § 1857c—5(c) (1970).

wealth of Massachusetts had failed to submit an acceptable plan to implement the national primary and secondary ambient air quality standards. We quote, at length, the First Circuit's discussion of the standard of review:

> Under § 706, we must determine whether EPA followed lawful procedures in evolving its plan; whether it acted within its statutory authority; and whether the plan is constitutional. If so, we must set aside the plan only if it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law". 5 U.S.C. § 706 (2) (A).
>
> In the following parts of this opinion we deal first with the procedural objections to the plan and later with the constitutional ones. In between we consider statutory objections and, most difficult of all, those objections addressed to the merits of the plan. The last objections, it is clear, are outside our province unless they show that EPA's decision was not based on consideration of relevant factors or else included a "clear error of judgment". *Overton Park, supra*, 401 U.S. at 416, 91 S. Ct. 814. We are not empowered to substitute our judgment for that of the agency.[5]
>
> The questions about the plan on review are of two types: the rationality of EPA's technical decisions (such as its determinations of local photochemical oxidant and carbon monoxide levels and the amount of reductions required to meet national standards), and the rationality of EPA's "control strategy", that is, the measures adopted to reduce emissions. The former present peculiar difficulties for nonexperts to evaluate. Yet "[our] inquiry into the facts is to be searching and careful", *id.*, and we must assure ourselves as best we can that the Agency's technical conclusions no less than others are founded on *supportable data and methodology and meet minimal standards of rationality. See* Section III, *infra.*

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Assuming EPA's technical determinations are reasonably based, we must decide whether the selected controls are arbitrary or capricious. In so doing, we must bear in mind that Congress lodged with EPA, not the courts, the discretion to choose among alternative strategies.[6] Unless demonstrably capricious—such as much less costly but equally effective alternatives were rejected or the requisite technology is unavailable—the Administrator's choices may not be overturned. . . .

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[5] The wisdom of the plan in the ordinary sense is outside our province. "We inquire into the soundness of the reasoning by which the [Agency] reaches its conclusions only to ascertain that the latter are rationally supported." *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 749, 92 S.Ct. 1941, 1946, 32 L.Ed.2d 453 (1972).

[6] "Looking to the future, and commanded by Congress to make policy, a rule-making agency necessarily deals less with 'evidentiary' disputes than with normative conflicts, projections from imperfect data, experiments and simulations, educated predictions, differing assessments of possible risks, and the like. The process is quasi-legislative in character, and one will search it in vain for those intermediate 'findings' of fact which mark the midway point in an adjudicator's linear march from raw evidence to single, ultimate conclusion." *Amoco Oil Co. v. EPA*, 501 F.2d 722, at 734-35 (D.Cir. 1974).[138]

Appropriately enough, Part III of the opinion is entitled, *Whether EPA Committed a Clear Error of Judgment in Computing the Need for Emission Reductions.* The First Circuit's emphasis on adequate data and appropriate methodology is fully in accord with our interpretation of the "arbitrary and capricious" standard.

In the case at hand, it seems obvious that the Administrator made "clear error[s] of judgment." This

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[138] 504 F.2d at 655-56 (empahsis added).

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conclusion is based upon a "searching and careful" inquiry into the facts underlying the determination that airborne lead will endanger the public health. At several points in the Administrator's reasoning we have found little or no evidence to support his conclusions, and at several points we have noted clear errors of a substantial nature in the Administrator's analytical and evaluative methodology and EPA's decision-making process. Several vital links in the chain are unsupported; for the Administrator to leap to the conclusion he did can only be termed arbitrary and capricious. We submit that "a clear error of judgment" has occurred,[139] as our concluding analysis of the evidence and methodology demonstrates.

IV. The Evidence

A. *This Court's Task*

It is of crucial importance to recognize that this court's task on review of agency rulemaking is twofold. One of these tasks is universally acknowledged. We must explore the evidentiary record to determine whether the statements and conclusions of facts have an adequate basis in the underlying evidence. However, an equally important role is our review of agency analysis in order to determine whether it is principled and reasonable. Properly understood, our role is not to review directly the

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[139] We find our colleagues do not differ materially with us on the standard for review. The court's opinion concludes, "[I]n the context of 'arbitrary and capricious' review, we shall reverse for a 'clear error of judgment' only if the error is so clear as to deprive the agency's decision of a rational basis." Court's opinion at 71 n.74. We believe here that the error of the Administrator was so clear as to deprive the agency's decision of a rational basis (as discussed in Part VI *infra*) and that the procedures of EPA were so faulty as to be "without observance of procedure required by law" (as discussed in Part II *supra*).

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evidence, but to review the agency's treatment and analysis of the evidence. Of course, in so doing we will defer to the agency's expertise and experience in the subject matter of the decision.

In our view, the court's treatment of the evidence neglects this second, equally important function of a reviewing court. Our colleagues' extended review of the evidence (in some respects much more extensive than EPA's own Third Health Document) at several points supplies reasons, distinctions, or modes of analysis that are otherwise absent from the Administrator's discussion. Just as agency counsel cannot supply a *post hoc* rationalization for agency determinations, neither can a reviewing court.[140]

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[140] In a footnote the court does pay lip service to this well-settled principle of judicial restraint: "Of course, [the rational] basis must be expressed by the agency itself *and not supplied by the court. SEC* v. *Chenery Corp.*, 332 U.S. 194, 196 (1947)." Court's opinion at 68 n. 73 (emphasis added). *Accord, Environmental Defense Fund, Inc. v. EPA*, where Judge Leventhal speaks for this court,

> The interests at stake here are too important to permit the decision to be sustained on the basis of speculative inference as to what the Administrator's findings and conclusions *might* have been regarding benefits. Sound principle sustains the practice of vesting choice of policy with the Administrator. Its corollary is that *the specific decision must be explained, not merely explainable,* in terms of the ingredients announced by the Administrator as comprising the Agency's policies and standards.

150 U.S. App. D.C. 348, 359, 465 F.2d 528, 539 (1972) (emphasis added). Here, too, the interests at stake are too important to permit EPA's decision to be sustained on the basis of speculative inference as to why the Administrator *might have* embraced certain studies and rejected others. "[T]he necessary articulation of reasons must appear in the preamble to the promulgated rule or in some other document of equally formal standing." 85 YALE L. J. 38, 71 (1975), *citing Associated Indus. of N.Y. State, Inc. v. United States*, 487 F.2d

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In order to avoid slighting either of our reviewing functions, our treatment of the evidence will track closely the Administrator's discussion and analysis of the evidence in the Preamble. To the extent necessary, the Administrator's discussion will be amplified by the Third Health Document. Rather than roving through the record looking for isolated snippets of evidence, only from these major starting points will we make the necessary comparisons with the underlying evidence.

B. *"A small but significant portion of the urban adult population . . . [is] over-exposed to lead."*

1. *The 40 ug Demarcation*

The Administrator introduces his analysis of the evidence with the following statement:

> Environmental lead exposure is a major health problem in this country. A small but significant portion of the urban adult population and up to 25 percent of children in urban areas are overexposed to lead. The lead exposure problem is caused by a combination of sources including food, water, air, leaded paint, and dust. The aggregate contribution of lead from all these sources poses a significant threat to health.[161]

Although the Preamble does not define what is meant by "overexposed to lead," Chapter Three (and to a lesser extent Chapter Four) of the Third Health Document explores the issue. The Document notes that blood lead levels, measured usually in terms of ug/100 g of blood (micrograms per hundred grams), are generally considered an appropriate index by which to assess the total

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342, 353 (2d Cir. 1973); *Dry Color Mfrs. Ass'n v. United States Dep't of Labor*, 486 F.2d 98, 105-07 (3d Cir. 1973); *Kennecott Copper Corp. v. EPA*, 149 U.S. App. D.C. 231, 234, 462 F.2d 846, 849 (1972).

[161] 38 FED REG. 33734, App. at 2.

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lead body burden. The general population carries blood lead levels of between 10 and 30 ug/100 g.[142] As exposure to environmental lead increases, blood lead levels increase slowly and in a nonlinear fashion. As a result, blood lead levels are a satisfactory index under constant exposure conditions but are less reliable under changing exposure conditions.[143] Clinical symptoms of lead poisoning usually do not appear until blood lead levels reach 80 to 100 ug/100 g or higher.[144]

The bulk of the discussion in Chapter Three relates to those studies which have attempted to identify the health effects associated with blood lead levels below those associated with lead poisoning. On the basis of those studies, EPA's staff tentatively concluded that "subclinical changes" *may* be associated with blood lead levels in the 40 to 60 ug/100 g range. The document is careful to emphasize that a 40 ug/100 g blood level "does not represent a sharp demarcation between health and disease." It rather represents a level above which it would be "prudent" to prevent further lead exposure.[145]

The court's opinion states that petitioners are contesting the setting of 40 ug/100 g as a precautionary level.[146] This is not the case. Petitioners' arguments have simply sought to emphasize the precautionary nature of the 40 ug level. They especially seek to emphasize EPA's own conclusion that no known functional injury or clinical effects occur in the 40 to 60 ug range and that whatever metabolic effects occur are "slight" and without clinical significance.[147] With these qualifications stated,

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[142] Third Health Document, IV-1, App. at 69.

[143] Third Health Document, IV-1 - IV-2, App. at 69-70.

[144] Third Health Document, III-2, App. at 55.

[145] Third Health Document, III-11, App. at 64.

[146] Court's opinion at 77-79.

[147] *See* Third Hearth Document, Table III-1, App. at 65.

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petitioners seem willing to concede for its limited purposes the 40 ug level as the line between normal and elevated blood lead levels.[148] Their central position, which we explore below, is that *EPA lacks a scientific basis for asserting the existence of blood lead levels in excess of 40 ug among a significant portion of the general adult population.*

2. *Over-Exposure in the General Adult Population*

Again we must turn directly to the Third Health Document, since the Preamble does not further amplify the basis for concluding that lead levels are indeed elevated in a significant portion of the population. As regards adults, the Health Document discusses the issue in the equivalent of one page of text and in two charts.[149] The Health Document begins by acknowledging that "due to limitations" on prior studies, "it is impossible to make precise estimates of the number of persons having blood lead levels within a given range." [150] These limitations include problems with the chemical procedure which analyzes lead in blood and deficiencies in quality control at laboratories. As the document concedes, "[r]eproducible results even within the same laboratory are not always obtained." [151]

Given the limitations on the underlying data, EPA's staff was still willing to conclude that certain groups, principally ones "occupationally exposed to automobile

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[148] Ethyl Supplemental Brief at 41-42; Nalco Supplemental Brief at 30-31; PPG/Du Pont Supplemental Brief at 15-16; NPRA Supplemental Brief at 5-6.

[149] Third Health Document, VII-1 to -2, Tables VII-1 & VII-2, App. at 142-43, & 145-46. By comparison, the court devotes four and one half pages of text and an eighteen page appendix to its discussion of the topic.

[150] Third Health Document, III-1, App. at 142.

[151] *Id.*

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exhaust," "frequently or characteristically" have elevated blood lead levels.[152] Petitioners vigorously attack this conclusion on two levels. First, they point out that EPA's data only supports a conclusion that certain occupational groups have higher blood lead levels as a result of occupational exposure. *It does not support a conclusion that a significant portion of the general urban population, not occupationally exposed to lead, has elevated levels.* In fact, petitioners emphasize that the only comprehensive study of the general urban adult population, the Seven Cities study,[153] found only three persons (or 0.15%) out of 1,935 persons tested had blood levels of 40 ug or higher.[154] This study was supported and directed in part by EPA and was completed recently (in 1972). Therefore, the study is particularly credible.

In addition, petitioners point to the study of Azar, *et al.*,[155] published in 1972, in which five groups of thirty subjects each were tested. One group consisted of Los Angeles cab drivers exposed to air lead levels of 6.1 ug/m^3. Despite these very high air lead levels, blood readings in this group averaged a normal 24.6 ug

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[152] Third Health Document, VII-1 to -2, App. at 142-43.

[153] Tepper, L. B., and Levin, L. S., "A Survey of Air and Population Lead Levels in Selected American Communities" (the Seven Cities study), Dept. of Environmental Health, College of Medicine, U. Cincinnati, Ohio (EPA Contract PN 22-68-28) (December 1972), Doc. 132, App. at 840.

[154] See excerpts from International Lead Zinc Research Organization, Inc. (ILZRO) submission of 9 March 1973 at 29, Doc. 836, App. at 2386. ILZRO was one of the joint sponsors of the study along with EPA.

[155] Azar, A., *et al.*, "Relationship of Community Levels of Air Lead and Indices of Lead Absorption," at 581-594, Proceedings of International Symposium on Environmental Health Aspects of Lead, Amsterdam (2-6 October 1972), Doc. 20, App. at 387.

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(±4.5 ug for one standard deviation).[156] Other groups had blood lead levels averaging from 13.8 ug to 22.4 ug. Of all 150 persons tested, only one subject showed a blood level over 40 ug and he was believed to drink moonshine whiskey.[157]

Second, petitioners attack the Administrator's reliance upon data derived from occupational categories exposed to unusual quantities of automotive exhaust, such as those working in parking structures, traffic tunnels, and closed garages, as well as those exposed to lead from sources other than the air, such as service station attendants and garage mechanics.[158] They question, implicitly at least, EPA's picking and choosing among the available data, *choosing data in which subjects are occupationally exposed to lead and rejecting data based upon samples drawn from the general urban adult population.* In effect, they argue that nation-wide restrictions upon lead additives must not be based upon merely precautionary blood levels in those occupationally exposed to unusually high amounts of lead.

We agree in substantial measure with petitioner's position. *EPA has presented no evidentiary basis for concluding that a significant portion of the general urban adult population has elevated blood lead levels.* Table VII-1 in the Third Health Document amply demonstrates this fact.[159] The Azar study of taxi drivers and office workers from Los Angeles, taxi drivers from Philadelphia, and persons from Barksdale, Wisconsin, and Starke, Florida, found *no one* (after excluding the imbiber of moonshine) with a level of 40 ug or higher. A sample of 55 "Women Living Near Freeways" uncovered

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[156] App. at 392.

[157] App. at 399.

[158] *See* Third Health Document, VII-2, App. at 143.

[159] App. at 145.

one person at 40 ug or above.[160] Two other composite urban samples of 423 and 833, respectively, found only 0.8% and 2.7% of the subjects with precautionary levels.[161]

Unexplained is the absence from Table VII-1 of the results of the Seven Cities study—1,935 persons tested and at most three with elevated blood levels. The court's opinion declares that "[p]etitioners rely heavily on the results of the so-called Seven Cities Study, which found a very small percentage of adults with elevated (in excess of 40 ug) blood levels. . . . The Adminitstrator, on the other hand, finds serious methodological flaws in the Seven Cities Study that limit its usefulness, 38 FED. REG. 33735. . . ." [162] We can understand the majority's anxiety to explain EPA's rejection of the Seven Cities study; however, the Administrator never discusses the studies on which he *does* rely for his conclusion that a significant portion of the urban adult population is over-exposed to lead. The discussion cited by the court relates to use of the Seven Cities study in an entirely different context, the presence or absence of a correlation between air lead levels and blood lead levels. Significantly, the methodological flaw being referred to by the Administrator is the fact that ". . . other sources of lead influencing blood lead levels were not adequately considered in the blood lead-air lead comparisons." [163] Although such a flaw might arguably affect the study's reliability as to the existence of a correlation, *it is quite irrelevant as regards the overall blood levels measured in the course of the study, which negate the hypothesis of over-exposure in the general adult population.*

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[160] *Id.*

[161] *Id.*

[162] Court's opinion at 80-81 (footnotes and citations omitted).

[163] 38 FED. REG. 33735, App. at 3.

The Seven Cities study clearly presents the second major defect in the Administrator's approach. *The Administrator chose among the available data without any explanation as to why—why he was relying upon certain studies and rejecting others.* No explanation is offered in either the Preamble or the three relevant paragraphs in the Third Health Document. This is not a case of a "clear error of judgment"; it is rather a case of a clear absence of judgment. On this score, our colleagues assert,

> Petitioners argue that the negative conclusions of the Seven Cities Study and several other studies should outweigh the positive indications of [certain other studies relied upon by EPA]. . . . The Administrator disagreed, and we cannot fault his conclusion.[164]

Thus, the court concludes that "[t]he problem here is one of choosing among the items of evidence."[165] We respectfully disagree. The problem here is really one of choosing among the items of evidence *and explaining why*! The Administrator disagreed with the negative conclusions of the Seven Cities study and several other studies, but never said why he disagreed. This is why we *can* fault his conclusion.

The court, however, again steps into the breach to offer its analysis of the studies:

> . . . [S]tudies of occupational groups are often particularly valuable in acting as an early warning system of possible effects on the public at large. The intensive exposure in particular occupations essentially accelerates the effects of long-term exposure of the general public and provides an identifiable, highly exposed, and readily accessible group of re-

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[164] Court's opinion at 83-84.

[165] *Id.* at 80.

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search subjects. *See* D. CLARK AND B. MACMAHON, PREVENTIVE MEDICINE 26 (1967) . . . .[166]

This rationalization of the Administrator's decision is purely *post hoc*. There is no basis for it in the Third Health Document.

The above is illustrative of the amazing lengths this court will go to to produce a decision for some uncertain, ill-defined, supposed environmental benefit. This court not only *commands* the Administrator to produce a decision by a certain date, but *rewrites* his decision to fill in the gaps when his logic falters.

The court, in addition, attempts to draw support from the fact that in the *Reserve Mining* case some of the evidence indicating the possibility of absorption of asbestos particles by the general public came from studies of asbestos workers. This reliance is entirely misplaced. We do not here suggest that the Administrator can not seek to reach a conclusion about the general public on the basis of studies of occupationally exposed individuals. Rather, we believe, that, if he has so concluded, he has not adequately explained how he did it. By contrast, the Eight Circuit undertook an extensive discussion of asbestos fiber exposure, relating occupational exposure to exposure by the general public through the ambient air. There is considered analysis on this precise issue in both the Eighth Circuit's opinion and the district court's opinion.[167]

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[166] *Id.* at 82-83.

[167] *See Reserve Mining Co. v. EPA*, 514 F.2d 492, 511-514 (8th Cir. 1975); *United States v. Reserve Mining Co.*, 380 F. Supp. 11, 39-54 (D. Minn. 1974) (supplemental memorandum). By our comparison, we do not mean to imply, as our colleagues assert, that there are no differences between *Reserve Mining* and the instant case. *See* Court's opinion at 83 n.90. We maintain only that both cases must be explained for the conclusions reached. Specifically we reject the

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In any event, the fact that such evidence proved relevant in *Reserve Mining* does not mean it would be relevant in this case. The issue of relevance is one for scientific inquiry and analysis. Such analysis was undertaken by the various witnesses, including especially the court-appointed expert, in *Reserve Mining. Such analysis is completely absent from the Third Health Document. This court can not now repair that defect. We can not perform this district court or administrative agency function.*

A crucial aspect of the Administrator's decision is deficient both because of its analysis and because of the absence of an evidentiary basis. On the record before us, we fail to see how the Administrator found an endangerment to a significant portion of the general urban adult population.

C. "*[A]bsorption of air lead does contribute to total lead exposure and when added to lead from other sources . . . results in total exposure that is excessive.*"

In promulgating the regulations, the Administrator stated the basic factual question to be resolved to be as follows: "*Is there a correlation between air lead levels and blood lead levels?*" [168] Acknowledging that the data failed to produce "consistent correlations," the Adminis-

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majority's conclusion that in the instant case the Administrator was not faced with a situation which "required that the propriety of reaching a conclusion about the public from occupational studies be explained." *Id.* In Judge Leventhal's words, the Administrator's decision "must be explained, not merely explainable." *Environmental Defense Fund, Inc. v. EPA*, 150 U.S. App. D.C. 348, 359, 465 F.2d 528, 539 (1972). *See* note 140 *supra.* We search in vain for this explanation in the Administrator's decision (*i.e.*, the Preamble) or the Third Health Document.

[168] 38 FED. REG. 33735, App. at 3 (emphasis in original).

trator nevertheless was able to reach the ultimate conclusion that auto lead emissions contributed significantly to excessive blood lead levels in adults. In our view, the record indicates that *the Administrator acted arbitrarily in choosing among the data relating to a possible correlation between air and blood lead levels.*

In the Preamble the Administrator explicitly relies upon the following studies to support the conclusion that there is a correlation between air lead levels and blood lead levels: the pilot lead isotope studies,[169] the unpublished study in Japan,[170] the Chamber studies,[171] and the Daines study.[172] Specifically rejected is the Seven Cities study[173] on the ground (previously noted) that "other sources of lead influencing blood lead levels were not adequately considered in the blood lead-air lead comparisons." *In neither* of the two epidemological studies *relied upon* by the Administrator, the Japanese study and the Daines study, *is there any indication that other sources of lead were controlled.* And yet, the Administrator in the

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[169] Rabinowitz, M., *et al.*, "Lead Metabolism in the Normal Human: Stable Isotope Studies," 182 SCIENCE 725 (November 1973), Doc. 113, App. at 704; Rabinowitz, M., *et al.*, "Studies of Human Lead Metabolism Using Stable Isotope Tracers," paper presented at EPA-NIEHS Conference on Low Level Lead Toxicity, Raleigh, North Carolina (1-2 October 1973), Doc. 113, App. at 678.

[170] Tsuchiya, K., *et al.*, "Study of Lead Concentrations in Atmosphere and Population in Japan," draft, undated, Doc. 468, App. at 1092.

[171] Knelson, J. H., *et al.*, "Kinetics of Respiratory Lead Uptake in Humans," Proceedings of the International Symposium on Environmental Health Aspects of Lead, Amsterdam (2-6 October 1972), Doc. 85, App. at 596.

[172] Daines, R. H., *et al.*, "Air Levels of Lead Inside and Outside of Homes," 41 INDUSTRIAL MEDICINE 26 (October 1972), Doc. 39, App. at 465.

[173] *See* note 153 *supra.*

Preamble, in an obvious reference to the Daines study, declares that "[w]hen comparable groups with similar lead intakes were studied," blood lead was higher among persons living in urban areas near highways.[174]

This is no minor slip on the Administrator's part. *His entire argument* in reply to criticism about the way in which he picked and chose among the various studies is that "[s]tudies which have come to contrary conclusions have generally failed to take into account the influences of other sources of lead on blood lead levels in people being studied."[175] The record indicates that *even the studies relied upon by the Administrator failed in this same respect.*

With regards to the Seven Cities study, the Administrator feebly attempts to gloss over his consistently selective approach with the following equivocal comment:

> [I]n the Seven Cities Study, urban-suburban differences in blood leads [*sic*] between comparable groups were consistently found which at least in part reflect differences in air lead exposure.[176]

The court's opinion, however, well recognizes the gravity of the Administrator's error and as a result offers for

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[174] 38 FED. REG. 33735, App. at 3.

[175] *Id.*

[176] *Id.* The Third Health Document devotes all of one sentence to the task of supporting the Administrator's comment:

> Based upon consistent differences between average blood lead levels in urban and suburban dwellers, the authors [of the Seven Cities study] concluded, "It is probable that these observations partially reflect lead absorption from ambient atmospheres differing in lead concentration . . . but that factors other than the atmospheric lead level are of relatively greater importance in determining the blood lead levels in population groups."

App. at 89.

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our edification a meatier, amplified version of this explanation as to why the Administrator embraces favorable studies possessing the same deficiency as the studies he rejects:

> The [epidemiological] studies before the Administrator [*e.g.*, the Seven Cities study] were of large groups of people; correlations were sought between blood level and exposure to lead in the ambient air. The studies were confounded, however, by the multiple sources of lead. Since diet accounts for a major portion of the body lead burden, an individual's blood lead level varies not only according to his exposure to lead in the ambient air, but according to his daily dietary intake of lead. Wide variations in dietary lead intake, which are common, can completely mask the effects of air lead absorption. Nonetheless, *none of the epidemiological studies could control or measure dietary lead intake.* This uncertainty in the data severely limited the usefulness of the broadly conceived epidemiological studies, and led the Administrator to rely instead on data limited to situations in which dietary exposure could roughly be termed constant.
>
> Following this rationale, the Administrator focused on the consistent relationship found between air and blood lead levels within particular metropolitan areas, rather than on the lack of such a relationship between areas. . . .[177]

No matter whether the court or the Administrator himself first came up with this explanation for EPA's inconsistent and selective approach to the evidence, it passes our understanding how anyone can find dietary control a problem in a comparison between greater Philadelphia and greater New York (thus justifying rejection of that data), but of no importance in a comparison be-

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[177] Court's opinion at 85-86 (footnote omitted and emphasis added). *Accord,* Court's "Appendix A" at A-13 to A-14 & n.15.

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tween Scarsdale and Harlem (thus justifying reliance on urban-suburban data from greater New York). The art of reconciling total inconsistencies has soared to new heights when this court can seriously conclude (1) that "dietary lead [can] be assumed relatively constant" [178] between the most affluent and the least affluent neighborhoods of greater New York City and (2) that "[t]he Administrator treated *all* the evidence in a consistent and rational manner." [179] The Administrator has thus utterly failed to present us with a reasoned and principled analysis of the evidence.[180] In fact, the Third Health Document does not even discuss the studies and analyses running counter to EPA's position; as a result, it is not strange that it finds no need to distinguish or reason them away.

To criticize EPA's overall analysis as arbitrary should not be construed as approval of each of the studies used by the Administrator to support his position. Petitioners have presented substantial criticisms of the methodology of those studies. They also point out that EPA has drawn inferences or conclusions from many of the studies which their authors were unwilling or unable to draw. We feel no need to discuss these criticisms in detail in light of our overall conclusion.

D. *The Contribution of Auto Lead Emissions to Blood Levels in Children—The Speculative Nature of EPA's Determination*

As a second subsidiary reason for adopting these regulations, EPA contends that contamination of dust and

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[178] Court's "Appendix A" at A-13.

[179] Court's opinion at 88 (emphasis in original).

[180] Likewise, the majority opinion fails to provide us with an acceptable analysis, but, unlike the Administrator, our colleagues may be excused since it is not their proper role to explain the actions of the Administrator. *See* note 140 *supra.*

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dirt by lead from automotive emissions is a significant source of lead exposure to children. This conclusion is based on the following chain of reasoning:

> a. High lead concentrations in dust and dirt are prevalent in urban areas.
>
> b. In most circumstances, lead from exhausts and not lead paint or lead from stationary sources is the primary source of lead in urban dust and dirt.
>
> c. Children, especially those between the ages of one and three, eat non-food objects, including dust and dirt. This phenomenon is known as pica.
>
> d. As a result of ingesting leaded dust and dirt, children "can be expected to absorb some of the lead into their bodies."

An alternative argument is also made that excessive lead levels are found among children who do not come from areas where peeling paint is common and therefore their lead levels *must* be accounted for by auto lead emissions.[181]

Neither the Administrator in promulgating these regulations nor EPA's scientists in the Third Health Document have explicitly stated that auto lead emissions *are* a significant source of lead to children. In fact, the Administrator states: "Ingestion of peeling paint has long been recognized as the primary cause of clinical lead poisoning in children."[182] The Administrator has quite frankly stated that the chain of reasoning outlined above is a hypothesis not yet completely proved:

> Currently, the contention that lead contamination of dust and dirt by automotive emissions is a significant source of lead exposure is a hypothesis consistent with information provided by a variety of

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[181] 38 FED REG. 33736 (6 December 1973), App. at 4.

[182] *Id.*

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> studies. However, at this time, not all links in the argument have been established beyond dispute and no single study has collectively inter-related all steps in the exposure process to conclusively inter-related [*sic*] all steps in the exposure process to conclusively prove or disprove the hypothesis. Despite the existing uncertainties, comments received from the majority of scientists not affiliated with industrial or environmental groups support the contention that dust is an important source of exposure.[183]

The conclusion drawn by EPA's scientists, after reviewing all the evidence submitted in the proceedings, is even more tentative:

> In conclusion, clinical experience indicates that leaded paint is primarily responsible for the great majority of overt clinical lead toxicity in children. There is, however, sufficient data to strongly suggest that sources of lead other than paint play an important role in childhood lead exposure. These other sources may be especially significant at levels of exposure below overt clinical poisoning.
>
> Lead in the air, and particularly lead in dust, are ubiquitous sources of lead which may well be important contributing factors to the problem. Exposure to dirt and dust sufficiently contaminated by lead could reduce significantly the quantity of additional lead exposure required to produce clinical poisoning in a child with other sources of exposure. Though exposure to lead contaminated dirt and dust from automobile exhaust, alone, has not been shown to be responsible for cases of overt lead poisoning, automotive lead has been related to undue lead absorption in children. At this time, it would be prudent to decrease the potential air and dust lead exposure. It should be recognized that further studies are necessary to better quantitate the sources of lead contamination in dust and dirt and the magnitude of

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[183] *Id.* at 33735-36, App. at 3-4.

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> the contribution that leaded dust and dirt make to both subclinical and clinical lead overexposure.[184]

The Administrator has implied that the large incidence of excessive lead exposure among children "known to not reside in homes where peeling lead based paint can be found . . . indicate[s] that in some circumstances dust lead is an important factor and at times may be the primary factor contributing to excessive lead exposure associated with subclinical if not clinical effects." [185] There is literally nothing in the record which accounts for these high lead levels among children who live outside of "the central city environment." Assuming that lead based paint was not the explanation, neither EPA's scientists nor the studies they evaluated could offer an alternative explanation, much less tie the excessive exposure to auto emissions. The Third Health Document identified "lead in food, water, pottery, toys, pencils, solder, etc." as possible explanations for excessive lead exposure in those cases where lead paint was not a problem.[186] It also noted that "[f]urther information is required to arrive at a definitive assessment of the significance of . . . [lead contaminated dust and dirt as a] source of lead contamination." [187]

Probably the best overall conclusion on EPA's dust and dirt hypothesis was made in one of EPA's own internal memorandums by two members of the Office of Planning and Evaluation to Dr. Kenneth Bridbord of the Office of Research and Monitoring:

> The reaction of this Office to the balance of Section VI, The Mechanism of Dustfall Lead Exposure, is an ambivalent one. We basically have no objec-

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[184] Third Health Document, VI-21 - VI-22, App. at 131-32.

[185] 38 FED. REG. 33736 (6 December 1973), App. at 4.

[186] Third Health Document, VI-13, App. at 123.

[187] *Id.*

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tions to the content of this Section; that is, we feel that it meets satisfactory standards of objectivity and quality as a scientific report in itself. On the other hand, *if the purpose of this section is to establish a direct line* between lead-contaminated dust and dirt from automotive exhausts and cases of lead poisoning *and to thereby support the proposed lead regulations, then we find it lacking.*

The report's conclusion concerning the bio-availability of lead from ingested contaminated dust and dirt is not at issue here. However, we should like to emphasize that *none of the studies cited directly implicated lead from automotive exhausts as being responsible for the harming of any human being.*[188]

Implicit in EPA's position is the premise that lead from auto emissions falls to the ground and mixes with the dust and the dirt *at those places where children are likely to play or be.* Petitioners concede that lead from auto emissions does fall to the ground, *e.g.*, the center of a six-lane highway. However, they contend it does not fall in those places where significant numbers of children usually spend their time.[189] They contend that lead paint and, in some circumstances, emissions of stationary sources account for lead in the dust and the dirt that children are likely to eat. Finally, they emphasize that lead paint (not auto emission lead) is the culprit pointed to by the available evidence.

We agree with petitioners' argument, but not, as our colleagues assert, because we refuse "to recognize that city children play regularly in the city streets." [190] Rather, we reject the Administrator's dust-fall hypothesis because we refuse to recognize that *preschool children* (the only

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[188] Doc. 352, App. at 1057 (emphasis added).

[189] Reply Brief for Petitioners in Nos. 73-2268 and 73-2269 at 17.

[190] Court's opinion at 92.

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children in which pica is a common phenomenon)[191] play in *heavily trafficked* city streets. In other words, we submit that (1) the older the child, the less likely it is that he or she will ingest the dust and dirt found in a city street, (2) the younger the child, the less likely it is that he or she will be playing in a city street—especially a *heavily-trafficked* city street, and (3) significant amounts of lead *from auto emissions* are only found in heavily trafficked city streets.

Recognizing the weakness of their position, our colleagues attempt to discount the importance of the Administrator's dustfall hypothesis,

> While the [dustfall] hypothesis is admittedly not proved as fact, we need not decide whether it would be sufficient by itself to support the low-lead regulations, for it is offered only in support of the evidence already presented.[192]

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[191] The NAS Report, on which the majority opinion relies, contains the following definition of "pica"

> The term "pica" has been defined as the repetitive ingestion of things that are not food (e.g., string, dirt, paper, putty, paint, clay and cigarette butts). It is important in a variety of accidental poisonings in *preschool* children. The behavioral biologic factors responsible for this *age-related* activity are not understood. Lourie and his associates have stressed disturbed parent-child relations as a factor that can intensify pica in the child, whereas Neumann has suggested that it may be a vestigial instinct. Lourie and associates and Sobel found that *the habit begins at the age of about 12 months*, that *it may persist until the age of 3-5 years*, and that it occurs in at least 50% of the children in both middle-class and poverty groups. Thus, pica is apparently a rather common behavioral activity in normal *preschool* children, and it may become intensified in response to stress.

NAS Report at 133 (footnotes omitted and emphasis added).

[192] Court's opinion at 88.

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Since we, unlike our colleagues, would not sustain the low-lead regulations on the basis of "the evidence already presented" (*i.e.*, the evidence discussed in sections IV. B. and C., *supra*), we can not avoid deciding whether the Administrator's dustfall hypothesis is sufficient *by itself* to support the regulations. Based on the three common-sensical assumptions stated above, we conclude that it is not even more likely than not that lead dustfall *from automobile emissions* is swallowed by preschool children with pica. Until, and if, the Administrator can at least establish this causal connection, we should reject his dustfall hypothesis.[193]

Based in part upon EPA's own assessment of the evidentiary record, it is undeniable that the dust and dirt hypothesis continues to be a speculative explanation of

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[193] The majority opinion states that "the *Reserve Mining* court held, a *reasonable* hypothesis *supported by evidence* is a sufficient basis for regulating under the 'will endanger' standard . . . ." *Id.* at 95 n.96 (emphasis added). We see no inconsistency between this statement of the Eighth Circuit's holding in *Reserve Mining* and our position in the instant case. We reject the Administrator's dustfall hypothesis because it is not a reasonable hypothesis and because its causal connection is not supported by the evidence. Since we are not familiar with the record (*i.e.*, the scientific evidence) relied upon by the *Reserve Mining* court, we can not say how that evidence compares with the studies relied upon by the Administrator in this case. Our colleagues, however, assert that the Administrator's hypothesis here was "undoubtedly . . . more support[ed] in studies already made than the hypothesis that justified regulation in *Reserve Mining*," and that in *Reserve Mining* the evidence did not establish the causal connection between the allegedly offensive pollutant (asbestos fibers) and the potential health hazard (cancer). *Id.* at 93-94. If the Eighth Circuit did, indeed, rest its decision on a less reasonable, less supported, hypothesis than the one involved in this case, we can only conclude that this case and *Reserve Mining* will soon have one more thing in common; they both will be wrongly decided.

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high blood lead levels among certain children. There is simply no evidence in the record which directly proves (used in its scientific sense) the hypothesis. EPA has thus had to argue that its hypothesis is *consistent* with the evidence. The fact is that there may be some evidence in the record that may be consistent with the hypothesis, but there is also a mass of evidence (as EPA acknowledges) that is inconsistent. Once again, *EPA has not even gone so far as to explain why it is relying on the "consistent" evidence and not relying on the "inconsistent" evidence.* This portion of the Administrator's determination is by any definition "arbitrary and capricious."

V. Conclusion

The regulations on fuel additives promulgated by the Environmental Protection Administrator should be held invalid: assuming the correctness of the Administrator's interpretation of section 211(c)(1)(A) of the Clean Air Act, his analysis reflected a clear error of judgment upon the available evidence. Under the standards of review in 5 U.S.C. §§ 706(a)(A), (C), and (D), the regulations should be set aside.[194]

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[194] Petitioners have raised other objections to these regulations which we do not reach:

(1) Did the EPA properly consider other technologically or economically feasible means of achieving emission standards under section 202 of the Clean Air Act?

(2) Did EPA adequately consider such alternative means of regulation as air quality criteria and state plans pursuant to sections 107 through 110?

(3) Was the EPA required to file an environmental impact statement or its functional equivalent?

(4) Has the EPA given adequate consideration to the adverse health consequences of lead reduction as required by section 211?

(5) Is the lead reduction schedule provided for in the regulations arbitrary and capricious?

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There is an uncomfortably large body of evidence, relied upon by EPA to support these regulations, which came into its possession just days before final promulgation. Further, EPA's practice of accumulating a mass of scientific documents of all types in its "public information" file, without designating on which information it would rely until the promulgation of the Third Health Document simultaneous with the regulations, is by no means the "notice" required by the Administrative Procedure Act. Thus, interested parties had no reasonable opportunity to question the methodology of the investigators; EPA counsel can thus point to the absence of rebuttal evidence and imply that all was well in the later studies. In light of the fact that EPA had been gathering evidence on airborne lead for three years, and that after each of the previous public comment periods EPA had been forced to reconsider its health position, the fact that so many of the studies that EPA uses to support its position were reported to the Agency less than sixty days prior to promulgation of the regulations, must necessarily give pause to this court.

The Administrative Procedure Act (5 U.S.C. §§ 706 and 553)[195] contemplates review of agency determinations after, at a minimum, an opportunity for public and governmental agency comment on all the evidence in the record. When this court mandated a decision within thirty days on a matter the Administrator had had under consideration for three years, there was no suggestion that the Administrator go to totally new, untested and uncommented upon data as a basis for his decision. The rationale behind such an order could only have been that the court believed the Administrator already not only had the necessary data in hand, but also had afforded the opportunity for informed public and other governmental department comment required in

[195] Sections 10e and 4 of the APA, respectively.

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valid agency rulemaking pursuant to section 553. If the Administrator believed that the data in the First and Second Health Documents, along with the searching criticisms received, would not support the decision he was about to make, then he could not lawfully make that decision. Nor could he make it on the basis of new and untested data in the Third Health Document.[196]

Turning from the procedure to the substantive basis of the decision, the supporting evidence and the analytical rationale applied by the agency, EPA falters on both prongs of its argument in regard to the impact of lead emissions on the general public health and on children. We find no plausible showing that lead in the air makes a "significant contribution to elevated blood lead levels" in either the general population or among children. The Preamble to these regulations itself states, "It is generally agreed that food is the major source of lead to the general population." This is backed by the conclusion of Dr. Carl Shy of EPA, that on the basis of the Seven Cities study[197] only three percent of the differential in blood lead levels between those who lived in urban areas and those who lived in the suburbs can be accounted for by

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[196] It is significant that the First Circuit in *South Terminal Corp. v. EPA* quoted the same portion of *International Harvester* (re the effect of comments on rulemaking) as does the court, yet in evaluating the degree of reliance EPA was entitled to place on an ambient air report, stated, "Moreover, it was published after the plan was announced and interested parties have not had an opportunity to criticize the findings." 504 F.2d 646, 669 (1st Cir. 1974). And later, in discussing the whole broad issue of the adequacy of EPA air measurements, the First Circuit said, "[T]he record as now constituted, made without specific consideration of the mentioned objection, leaves us in doubt as to whether or not there is a rational basis for EPA's estimate . . . ." 504 F.2d at 666.

[197] *See* note 153 *supra*.

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the air lead gradient" between the two areas.[198] As for children, the preamble states, "Ingestion of peeling paint has long been recognized as the primary cause of clinical lead poisoning in children." As we pointed out at the outset,[199] only if auto lead emissions can be shown to contribute significantly to blood lead levels can it logically follow that a reduction or elimination of auto lead emissions would contribute significantly to solving the problem of lead in the human body.

We judges may be, as we are sometimes reminded, without scientific background or access to expertise, but we think this brand of administrative agency action should be readily apparent—and equally abhorrent—to any appellate judge. To detect and set aside agency action based on such shoddy foundations, not to engage in rival scientific calculations or substitute judgment, is the function of a reviewing court.

We appreciate the quandry in which the Administrator found himself after three years of pondering this question. Beset on all sides by those urging the Administrator to take action, to ban or limit drastically the use of lead in gasoline, confronted by the arguments of those who asserted that such action was completely unjustified, attempting in the First Health Document and in the Second Health Document to postulate a scientific basis for the action he had tentatively decided to take only to have the scientific bases of his action riddled by the analyses of scientists in all other departments of the Government commenting thereon, and confronted finally by an order of this court that he act one way or another in a period of thirty days, the Administrator found him-

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[198] Transcript of Lead Portion of Meeting of EPA Hazardous Materials Advisory Committee, Washington, D.C., 26 February 1973, Doc. 325, App. at 991-92.

[199] *See supra* at 52.

self with the question "whether . . . to take arms against a sea of troubles, and by opposing end them." [200] So the Administrator acted, in reliance primarily on data only partially analyzed by his own staff and not commented on according to the prescribed procedure or by the most knowledgeable parties. The result was, Hamlet-like, a blind stab through a curtain of ignorance, inflicting anguish, but in our judgment not rationally solving any problem.

It should be understood that our view would not prohibit EPA from regulating lead additives under section 211(c)(1)(A) at some point in the future, should evidence sufficient to meet the statutory standard be developed and should action appear appropriate. On the present record, however, we cannot agree that EPA has properly decided that lead additives in gasoline will cause emissions which "will endanger the public health."

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[200] Hamlet, Act III, scene 1, line 57 *et seq.*

APPENDIX

Title 40—Protection of Environment

Chapter I—Environmental Protection Agency

Part 80—Regulation of Fuels and Fuel Additives

Control of Lead Additives in Gasoline

* * * *

Health implications of airborne lead—Introduction. The issue concerning the contribution of automobile lead exhausts to the country's lead exposure problem is complex and controversial. In order to complete a fair assessment of this problem, EPA has made a concentrated effort to obtain and review all the medical and scientific evidence. The Agency has repeatedly requested information and comments from the medical and scientific communities as well as the general public. Since the reproposal of the regulations, information gathered through the comment period on the reproposed regulations, earlier comment periods on the originally proposed regulations, and surveys of relevant studies by EPA personnel have been thoroughly reviewed and evaluated by a task force of EPA medical experts and scientists. A paper entitled "EPA's Position on the Health Implications of Airborne Lead" sets forth in detail the Agency's evaluation that there is a health basis for reducing the use of lead in gasoline. A copy of this paper is available from the Publications Section, Environmental Protection Agency, 401 M Street SW, Room 238W, Washington, D.C. 20460.

General summary of health issue. Environmental lead exposure is a major health problem in this country. A small but significant portion of the urban adult population and up to 25 percent of children in urban areas are over-exposed to lead. The lead exposure problem is

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caused by a combination of sources including food, water, air, leaded paint, and dust. The aggregate contribution of lead from all these sources poses a significant threat to health. However, it is extremely difficult to determine what percentage of the problem each separate environmental factor contributes. Since there are additive sources whose importance varies considerably among individuals it is likewise difficult to determine what impact would be achieved by partial or total reduction of lead from any source. Should the lead in all sources be reduced, however, it seems clear that the situation would be substantially improved. Leaded gasoline is a source of air and dust lead which can be readily and significantly reduced in comparison to these other sources. It is also one of the few lead sources not yet subject to any controls other than EPA's lead-free gasoline regulations.

Lead from gasoline accounts for approximately 90 percent of airborne lead, total lead additive usage being well over 200,000 tons a year. Lead from stationary sources and deteriorating leaded paint from buildings, combined with lead from gasoline cause high lead levels in dirt and dust. Of these sources, lead from gasoline is the most ubiquitous source of lead found in both the air and the dirt and dust in urban areas. Human exposure to this lead takes place by inhalation and by ingestion of dirt and dust contaminated by air lead fallout. Since exposure to lead among the general population is widespread, it is reasonable that efforts be made to reduce preventable sources of lead exposure including lead emissions resulting from lead in gasoline.

Many of those disagreeing with the reproposed regulations based their comments on EPA's failure to show sufficient evidence of adverse health effects specifically caused by the use of lead additives in gasoline. While most agree that the combustion of leaded gasoline causes an increase in the amount of lead in the environment,

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they do not believe that lead in gasoline represents a sufficient endangerment to health or a sufficient risk to the environment to warrant promulgation of controls. The arguments against the position set forth in EPA's reproposed regulations include the following: (1) EPA has failed to show a clear correlation between lead levels in the air and those in the blood of exposed individuals; (2) lead from dust and dirt does not represent a significant threat to body burden of lead; (3) leaded paint is the primary cause of childhood lead poisoning and lead in gasoline does not play an important role in and lead poisoning or excessive lead exposure; (4) lead in food and water and not airborne lead are the principal sources of lead to the general population.

A discussion of the four major areas of criticism and a summary of the significant new information received since the regulations were reproposed are provided below.

I. *Is there a correlation between air lead levels and blood lead levels?* A portion of the comments received were critical of EPA's reproposed regulation on the basis that consistently strong correlations have not been found between air lead and blood lead levels. The conclusion expressed by many comments is that except for persons whose occupations bring them in close contact with environmental lead, exposure to airborne lead does not contribute to increased blood lead levels and does not pose a significant threat to health.

These comments cite several studies which did not demonstrate a strong correlation between air lead and blood lead levels. For example, The Seven Cities Study did not show a close correlation between increase in blood lead levels and simultaneous increases in air lead exposures. Blood lead levels were lower among the New York City residents studies than the Philadelphia residents, despite the fact that air lead exposures among the New York

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residents were actually greater than those in Philadelphia. Also cited as evidence against EPA's position is the observation that despite significant increases in the use of lead in gasoline in recent years there have been no discernible increases in blood lead levels of populations so exposed.

Residential differences in blood lead levels have also not always corresponded to differences in air lead exposures. For example, studies of primitive populations, as well as studies of rural U.S. populations, have shown that the blood lead levels in some of these groups are as high or higher than those of persons living in industrial areas, even though the air lead levels in those rural areas should have been much lower. A comparison between London day and night taxi drivers has also shown no significant differences in blood lead levels but did find differences in exposure to carbon monoxide suggesting that despite the possibility that air lead exposure in the day may have been higher than at night, this was not reflected in blood lead increases. However, differences in smoking intensity, as well as actual differences in air lead exposure between groups, could explain these results and neither were measured.

In summary, a number of comments have criticized EPA's position on the basis that there is not a good correlation between air lead exposure and blood lead levels.

The Agency has weighed against these criticisms studies which have shown that airborne lead does contribute significantly to lead exposure in the general population. For example, using a pilot lead isotope approach, preliminary data show that airborne lead at 2 $\mu g/m^3$ can contribute as much as ½ to total lead exposure in man. This result is consistent with data concerning the deposition of lead particles in the pulmonary tract and the absorption of such particules into the blood stream.

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An unpublished study in Japan similar to the Seven Cities Study, but which has not yet been completely analyzed, has preliminarily demonstrated that airborne lead exposures below 2 $\mu g/m^3$ affect blood lead levels.

Chamber studies in carefully controlled environments, have shown significant increases in blood lead of men exposed to air lead slightly greater than 3 $\mu g/m^3$.

Differences in the blood lead levels between urban and suburban residents in the same geographic area have been found. When comparable groups with similar lead intakes from other sources besides air were studied, blood leads were consistently higher in urban areas and near highways where air lead concentrations were greatest. Thus while correlations between blood lead levels and air leads at lower exposure levels are not always good, the evidence indicates that air lead does contribute to general population lead exposure.

Failure to find consistent correlations does not in the Administrator's judgment invalidate the above conclusions. Studies which have come to contrary conclusions have generally failed to take into account the influence of other sources of lead on blood lead levels in people being studied. In the Seven Cities Study, for example, these other sources of lead influencing blood lead levels were not adequately considered in the blood lead-air lead comparisons. EPA has re-analyzed the Seven Cities Study and has found that air lead was a significant, though not the most influential factor affecting blood lead levels. Further, in the Seven Cities Study, urban-suburban differences in blood leads between comparable groups were consistently found which at least in part reflect differences in air lead exposure.

In summary, absorption of air lead does contribute to total lead exposure and when added to lead from other sources such as food and water results in total

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exposure that is excessive. Thus, the partial removal of lead from the air will help to reduce the degree of excess lead exposure which currently exists among adults and children in the United States.

II. *Does dust lead contribute to lead poisoning in children?* Many comments received by the Agency express the viewpoint that the primary cause of lead poisoning in children is ingestion of lead-based peeling paint. Investigations of cases of clinical lead poisoning in children have repeatedly demonstrated peeling leaded paint as the major source of exposure. Since peeling leaded paint has consistently been observed in the environment of lead poisoned children, many commentors thought it unlikely that lead in dust and dirt could make a significant contribution to this problem. They also point out that lead in dust could be caused by peeling or erosion of leaded paint in or near a home.

One commentor cites X-ray studies of the abdomen among children with lead-poisoning as showing paint chips in the majority of instances. Another argues that differences in blood lead levels between Black and Puerto Rican children could not be explained by exposure to different quantities of lead in dust. Further, studies have shown that animals do not absorb lead from dust as readily as they absorb lead from paint.

Commentors have criticized the Agency for considering that the El Paso Study supports the dustfall hypothesis related to lead in gasoline. In the El Paso Study, children living near a leadsmelter were examined for blood lead levels and for sources of lead in their environment These results showed that children living nearest the smelter had the highest blood lead levels and that dust lead was a probable major cause. Many commentators, however, considered the El Paso Study applicable only to stationary lead sources and not to lead in gasoline which is dif-

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ferent in particle size and chemical composition from smelter-emitted lead.

EPA recognizes the importance of leaded paint as a source of lead exposure for children and that it is the primary cause of clinical lead poisoning. However, based on the evidence available to it, EPA does not believe that leaded paint is the only significant source of lead contributing to excessive lead exposures in children. The Agency's position is that numerous sources contribute to childhood exposure including lead in food, water, air, dust, and dirt as well as paint. Among these sources, contaminated dust and diret from motor vehicles exhausts are believed to be important exposure routes.

Currently, the contention that lead contamination of dust and dirt by automotive emissions is a significant source of lead exposure is a hypothesis consistent with information provided by a variety of studies. However, at this time, not all links in the argument have been established beyond dispute and no single study has collectively inter-related all steps in the exposure process to conclusively prove or disprove the hypothesis. Despite the existing uncertainties, comments received from the majority of scientists not affiliated with industrial or environmental groups support the contention that dust is an important source of exposure. This is based on the following evidence :

A. Environmental sampling in a number of cities has demonstrated the ubiquitous presence of lead contaminated dust in urban areas. These measurements were taken inside and outside of buildings including homes and schools. Dust lead measurements outside homes commonly ranged from 0.1 to 0.5 percent lead by weight. Measurements well in excess of 0.5 percent have also been recorded. Inside homes, samples were found to contain lead contents ranging from 0.05 to 0.2 percent and

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in some instances as high as 0.5 percent. Current Federal regulations have already established that lead concentrations in paint in excess of 0.5 percent represent a definite hazard to children and serious consideration is being given to reducing the allowable level to 0.06 percent. In testimony before the United States Senate, Dr. Merlin DuVal, at the time Assistant Secretary of Health and Scientific Affairs at HEW, commented on an appropriate safe level for lead in paint:

> Based on information now available to us, we are satisfied that it is technologically feasible, and desirable from a health viewpoint to move toward the .06 percent standard recommended by the American Academy of Pediatrics.

B. As was stated above, high lead concentrations in dust are prevalent in urban areas. It is not clear in all instances, which sources are contributing most to this contamination. Comments received by the agency point out that high lead levels in some cases may be caused by the chipping or peeling of leaded paint from interior and exterior surfaces. EPA agrees that this is true. In other cases, the lead dust content is clearly the result of lead emission from stationary sources such as smelters. However, EPA believes an important and the most ubiquitous source of lead in dust is the exhaust of automobiles using leaded gasoline. Annually, over 200,000 tons of lead are used as additives in gasoline. The vast majority of this lead is emitted into the environment. Although significant amounts of lead remain airborne for extended periods of time, evidence indicates that a large quantity of the exhaust lead rapidly settles to the ground within several hundred feet of the source. Measurements of lead in dust and soil further indicate that lead content decreases with increased distance from the roadway. It has also been found that dust lead levels in homes near heavily traveled roadways are significantly higher

than in comparable homes located along side streets. It should be noted that the majority of studies reporting high levels of lead in dust and dirt did not associate sources of peeling leaded paint or stationary lead sources with the lead dust measurements. Accordingly, the Agency believes that in most circumstances lead from automobile exhaust is the primary source of lead in dust and soil in urban areas.

C. The general environment of urban children commonly includes dirt and dust contaminated with lead. A large percentage of children, especially between the ages of one and three years, are known to ingest non-food objects in their mouths. It has been demonstrated that children living in high dust lead environments have greater quantities of lead on their hands than children living in less contaminated environments. The existence of leaded dust on the hands of urban children has been high-lighted by the common occurrence of inadvertent lead contamination of finger prick blood lead specimens taken from these children.

D. Children who ingest leaded dust and dirt can be expected to absorb some of the lead into their bodies. Though it is difficult to determine the precise amount of lead that would be absorbed, animal experiments suggest that appreciable quantities of this lead, whether from smelters, paint or gasoline exhaust, are absorbed. Further, it has also been shown that at least some children residing in environments heavily contaminated by leaded dust and dirt absorb enough to suffer from subclinical and even clinical effects of lead overexposure. This was particularly true in the case of El Paso, mentioned above. Though the lead source was a smelter, animal studies indicate that lead in dust due to leaded gasoline would be absorbed in quantities comparable to that emitted by the smelter. Another study from Charleston, South Carolina indicates that children residing in homes near high

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soil lead concentrations had a greater frequency of lead poisoning than children residing in less contaminated areas. This study suggests that lead from soil was absorbed, althought it is not clear what sources were primarily responsible for those high soil lead levels. It should be further noted that instances such as those above, coupled with known high levels of lead in dirt and dust, indicate that children could easily ingest enough lead by this route to be significant.

E. Various studies indicate that cases of lead poisoning and significant over-exposure are not always associated with urban home environments in which sources of peeling or chipping leaded paint were observed. These studies include children residing primarily in inner city areas. Admittedly children may be exposed to peeling or chipping leaded paint in environments away from their own homes. However, since several recent studies indicate that up to 60 percent of children with excessive lead exposure are known to not reside in homes where peeling lead based paint can be found, it is unlikely that peeling paint exposure away from the homes accounts totally for this difference. Furthermore, extension of blood lead screening programs outside of slum areas indicates that the lead exposure problem is found in children residing in higher income areas where peeling paint is not frequent and exposure to this source away from the home is less likely. In conjunction with these findings, residence near roadways have been found to contain higher quantities of lead than those measured away from the road. Findings such as these indicate that in some circumstances dust lead is an important factor and at times may be the primary factor contributing to excessive lead exposure associated with subclinical if not clinical effects.

F. Clinical symptoms resulting from very high lead exposure in children are known to be associated with permanent neurologic damage. It has also long been sus-

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pected, but not proven beyond doubt that lead exposures below those sufficient to cause clinical symptoms in children are also harmful. In particular it has been observed that physiologically significant biochemical changes occur in children with excessive exposures below clinical toxicity and it has been proposed that these changes are reflective of subclinical changes that precede overt disease. Recently available scientific information, though far from completely resolving this issue, supports the view that adverse effects due to lead in children are not confined only to situations in which overt clinical symptoms of lead poisoning occur. Included in these findings are increased subtle neurological impairments among children more highly exposed to lead below levels known to cause clinical disease.

III. *Will a reduction of lead in gasoline reduce the incidence of clinical lead poisoning in children?* Ingestion of peeling paint has long been recognized as the primary cause of clinical lead poisoning in children. This position has been expressed in many comments received by the in the field of lead poisoning. For this reason, numerous comments have questioned the need to reduce lead in gasoline on the basis that this action would have little if any impact on reducing the incidence of clinical lead poisoning in children.

While EPA recognizes the importance of leaded paint as a source of lead for children and has supported governmental efforts to reduce this risk, the findings of several studies suggest that lead poisoning can develop in the absence of significant sources of leaded paint. Though this possibility does not affirm that reducing lead in gasoline will reduce the incidence of lead poisoning in children it indicates that lead in gasoline may, in conjunction with other nonpaint sources, contribute to the development of lead poisoning. Whatever the impact this reduction may

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have upon clinical lead poisoning, the action will significantly reduce lead exposure among children.

EPA is also concerned about the probability that children exposed to lead at levels below those associated with clinical poisoning are also being adversely affected. Several effects identified as subclinical lead effects include impairment of fine motor functions, and altered behavior.

It is noteworthy that in a significantly large percentage of excessive lead exposure cases (up to 50 percent in some instances) peeling lead based paint in the home cannot be identified as a source of the exposure. Thus, while leaded paint is recognized as the major cause of childhood lead poisoning, it is not clear that leaded paint is singly responsible for the large degree of excess childhood lead exposure in this country.

IV. *Excess lead exposure among the general population could result from a combination of lead sources, not one of which by itself is sufficient to be a problem. Under these circumstances, would it not be preferable to formulate a control strategy based upon reducing lead levels among those sources that contribute the most to this total exposure?* It is generally agreed that food is the major source of lead to the general population. A World Health Organization expert committee reports that according to the results of total diet studies in the industrialized countries, the total intake of lead from food generally ranges from 200-300 ug per person per day. WHO further states that based upon available data, these levels are similar to those found in the past 30-40 years and that no upward trend in lead levels in food is evident.

This information suggests that the level of lead in food has remained relatively constant in recent times. Though lead in food would certainly contribute to total lead exposure for the general population, lead in food is probably not the source that is most readily reduced in the

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event that total exposure to lead is excessive. According to WHO, "Any increase in the amount of lead derived from drinking water or inhaled from the atmosphere will reduce the amount that can be tolerated in food. The lead in air is probably the contribution that is most accessible to action for reducing the total body burden of lead, especially where this fraction is large compared with that absorbed from food."

V. *What new information has become available since reproposals of the regulation and as a result of the additional comment period?* The majority of comments addressed the evidence presented by EPA in support of its proposed regulation and did not introduce new evidence. The number of comments received were approximately evenly divided between those in favor and those against. The bulk of comments critical of EPA's health position was submitted by industry or industry affiliated scientists. Independent scientists who commented, not affiliated directly with the industry or environmental groups, were in favor of the regulation by approximately 2/1. Most favorable comments, though often from scientists knowledgeable in the field of lead, provided testimonial support rather than new evidence. Most new data that either was presented in comments or which subsequently became available to EPA does support the need to reduce lead emissions from automobiles. Among these latest data are the following:

(1) Studies of subclinical lead effects in children continue to suggest that fine motor function and behavior are affected. Though this issue is not completely resolved, the new data emphasize the potential subclinical risk.

(2) It has been reaffirmed that high dust lead levels, up to 1% lead content, have been found in children's play areas, inside schools and in homes.

(3) New evidence reaffirms that high dust lead levels can be caused by leaded gasoline. A recent study in Ro-

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chester, New York, demonstrates that high dust lead levels in homes are not always associated with peeling paint and that house dust lead levels are higher in urban than suburban homes. A study in Vermont has shown that higher concentrations of lead in house dust are found in homes located near busy roads compared to homes on sidestreets. This latter point is consistent with the previously known fact that air lead fallout decreases with increased distance from roadways. A study by EPA in New York City indicates that higher household dust and soil lead levels are found in areas with greater dust lead fallout from the air as compared to areas with little lead fallout.

(4) Young children living in homes with high dust lead contents have been found to have more lead on their hands than children in homes with low dust lead content. This finding provides an important link in the dust fall lead hypothesis. The finding is consistent with observations that finger prick blood-lead specimen taken from children are routinely contaminated by lead that is present on the fingers.

(5) Studies continue to indicate that a high degree of exposure to environmental lead is not confined to inner city areas. Cases of over-exposure continue to be reported from areas in which leaded paint would not be expected to be the predominant factor.

(6) Studies from Newark, New Jersey, observed that the frequency of lead poisoning and undue lead exposure is doubled among children living close to major roadways compared to children living farther away.

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38 FED. REG. 33734-33737 (6 December 1973); App. 2-5.